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**Power Medical  
Interventions®**

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*Annual Report 2007*



*A Continuous Flow of Innovation*



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\*FDA 510(K) clearance not yet obtained

## *To Our Shareholders*

2007 has been a very exciting year for Power Medical, as we further improve our position at the forefront of technology development in the minimally invasive surgery marketplace. In October, we successfully completed our IPO, which provided us with funds to support the build out of our infrastructure. During 2007, we continued our transition from contract manufacturing to self manufacturing in our Langhorne facility. We also introduced the next generation of Intelligent Surgical Instruments™ with the launch of our i60 and iDrive products.

We experienced a slight decrease in revenues compared to 2006, but were not discouraged as it was a result of our decision to cease sales of the PLC 60 product mid year in anticipation of the launch of the i60 at the end of September. Our gross profit, on the other hand, increased to \$1.1 million or 14.5% of sales for the year, from a negative \$2.2 million in 2006. The improvement in our 2007 gross profit and our gross margin percentage reflects the benefits of our continuing transition from contract manufacturing to self manufacturing and increased efficiency of our manufacturing operations.

With the expansion of our worldwide sales force and increased marketing efforts to support our i60 and iDrive product launch and ongoing market activities, we are well positioned to educate the market and penetrate the marketplace. In addition, with our additional manufacturing capabilities, we feel we are well positioned to support our future growth.

**Our strong belief in the future growth opportunity for Power Medical stems from the strength of our Intelligent Surgical Instruments technology platform.**


Our strong belief in the future growth opportunity for Power Medical stems from the strength of our Intelligent Surgical Instruments technology platform. With the launch of the i60 and iDrive, our second generation technology, we moved from a tethered platform, requiring a separate D/C powered console and a flexible shaft to a self contained wireless lithium ion battery powered platform. We believe that compared to conventional endomechanical devices, our Intelligent Surgical Instruments offer significant benefits to surgeons, including greater precision, operating consistency, superior compressive force, improved access to anatomical sites, and ease of use. Our Intelligent Surgical Instruments are the first and only endomechanical instruments to incorporate digital technology. Our platform has been used in tens of thousands of surgical procedures in more than 350 hospitals worldwide. Our goal is to become the leading worldwide supplier of intelligent surgical instruments used in minimally invasive surgery and natural orifice transluminal endoscopic surgery (NOTES), a less invasive surgical technique. Medtech Insight recently estimated that by 2010 the number of annual procedures performed within our current areas of clinical focus in the US alone will grow to 697,300, creating a solid market opportunity for our products.

Looking ahead to 2008, we intend to launch a number of new products. These will include our i45 linear stapler, a shorter version of our i60, using blue and green staple sizes and designed to offer access to small, tight anatomical spaces, such as the thorax for lung resections and lung transplants and the deep pelvis for colon and rectal surgery. We will also be launching our much anticipated i45v, a linear stapler using white staples and designed for use on pulmonary arteries, veins and other vascular structures throughout the circulatory system.

In addition, we are working on a new device for minimally invasive bariatric surgery. The device will enable a new sleeve gastrectomy procedure for bariatric surgery. The device which will be used in this procedure is a modified i60 requiring only a software change from our existing product. We will be doing some bench testing in a pre-clinical setting in the second quarter and will move into clinical setting pending successful results of the pre-clinical work.

We are also pleased to announce the formation of PMI Endoscopy. PMI Endoscopy will pursue Intelligent Surgical Instrument applications in the GI endoscopy marketplace. We expect that these indications will include Gist tumor removal, cystogastrostomy closure, polyp excision, gastrotonomy and colostomy closures in NOTES procedures and related procedures.

We will make investments across the organization to ensure we continue to drive product innovation, expand our market penetration, increase our operating efficiency and deliver improved financial results. On behalf of our Board of Directors and the Power Medical management team, I would like to thank all of our employees and our shareholders for their dedication and commitment.



Michael P. Whitman, *President and Chief Executive Officer*

**Our goal is to  
become the leading  
worldwide supplier of intelligent  
surgical instruments used in  
minimally invasive surgery  
and natural orifice trans-  
luminal endoscopic  
surgery.**

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark one)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended: December 31, 2007

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Commission file number: 001-33770

**POWER MEDICAL INTERVENTIONS, INC.**

(Exact name of registrant as specified in its charter)

**DELAWARE**

(State or other jurisdiction of  
incorporation or organization)

**23-3011410**

(I.R.S. Employer  
Identification Number)

**2021 Cabot Boulevard  
Langhorne, Pennsylvania 19047  
(267) 775-8100**

(Address, including zip code, and telephone number, including  
area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class

Name of each exchange on which registered

Common Stock, \$0.001 par value

The Nasdaq Stock Market, LLC (Nasdaq Global Market)

Securities registered pursuant to Section 12(b) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☐  
(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2007, the last business day of our most recently completed second fiscal quarter, our common stock was not listed on any exchange or over-the-counter market. Our common stock began trading on the Nasdaq Global Market on October 26, 2007. The number of shares of our common stock outstanding as of March 28, 2008 was 17,107,052.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of our proxy statement for use at our 2008 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

**POWER MEDICAL INTERVENTIONS, INC.**  
**FORM 10-K**  
**FOR THE FISCAL YEAR ENDED DECEMBER 31, 2007**  
**INDEX**

	<u>Page</u>
<b>PART I</b>	
Item 1. Business . . . . .	1
Item 1A. Risk Factors . . . . .	22
Item 1B. Unresolved Staff Comments . . . . .	42
Item 2. Properties . . . . .	42
Item 3. Legal Proceedings . . . . .	42
Item 4. Submission of Matters to a Vote of Security Holders . . . . .	43
<b>PART II</b>	
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities . . . . .	44
Item 6. Selected Consolidated Financial Data . . . . .	45
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations . . . . .	46
Item 7A. Quantitative and Qualitative Disclosures About Market Risk . . . . .	59
Item 8. Financial Statements and Supplementary Data . . . . .	F-1
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure . . . . .	60
Item 9A. Controls and Procedures . . . . .	60
Item 9B. Other Information . . . . .	60
<b>PART III</b>	
Item 10. Directors, Executive Officers, and Corporate Governance . . . . .	61
Item 11. Executive Compensation . . . . .	61
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters . . . . .	61
Item 13. Certain Relationships and Related Transactions and Director Independence . . . . .	61
Item 14. Principal Accountant Fees and Services . . . . .	61
<b>PART IV</b>	
Item 15. Exhibits and Financial Statement Schedules . . . . .	62
Signatures . . . . .	66

## PART I

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains forward-looking statements. These statements may relate to, but are not limited to, expectations of future operating results or financial performance, capital expenditures, introduction of new products, regulatory compliance, plans for growth and future operations, as well as assumptions relating to the foregoing. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. These risks and other factors include, but are not limited to, those listed under "Risk Factors." In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "intend," "potential," "might," "would," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. Actual events or results may differ materially.

We believe that it is important to communicate our future expectations to our investors. However, there may be events in the future that we are not able to accurately predict or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Except as required by applicable law, including the securities laws of the United States and the rules and regulations of the Securities and Exchange Commission, or SEC, we do not plan to publicly update or revise any forward-looking statements contained in this Annual Report on Form 10-K after we file this Annual Report on Form 10-K, whether as a result of any new information, future events or otherwise. Before you invest in our common stock, you should be aware that the occurrence of any of the events described in the "Risk Factors" section and elsewhere in this Annual Report on Form 10-K could harm our business, prospects, operating results and financial condition. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

#### Item 1. *Business.*

##### Overview

We design, manufacture and market our SurgASSIST® system of computer-assisted, power-actuated endomechanical surgical instruments, which we refer to as Intelligent Surgical Instruments™. Surgeons use our Intelligent Surgical Instruments for cutting, stapling and tissue manipulation in a variety of procedures in open surgery, minimally invasive surgery, or MIS, and in the emerging field of natural orifice transluminal endoscopic surgery, or NOTES. We believe that, compared to conventional endomechanical devices, our Intelligent Surgical Instruments offer greater precision and consistency, superior compressive force, improved access to anatomical sites and enhanced ease of use. To our knowledge, we are the only company to apply digital technology to the field of endomechanical surgical instruments. Our SurgASSIST system has been used in at least 30,000 surgical procedures in more than 350 hospitals and medical institutions worldwide.

Endomechanical devices are used in millions of surgical procedures each year to cut tissue, close wounds and reconnect tubular anatomical structures. However, we believe that conventional, manually operated endomechanical devices have inherent shortcomings that can limit their efficacy and adversely affect clinical outcomes. We founded Power Medical Interventions to address these shortcomings and to improve surgical outcomes by introducing the next generation of endomechanical instruments, designed specifically for the rapidly evolving field of minimally invasive surgery.

Our SurgASSIST surgical platform includes a suite of endomechanical devices in a variety of linear, right angle and circular configurations designed to meet specific surgical requirements. Each of these Intelligent Surgical Instruments employs our novel micro-robotic and digital technologies to

enable the remote application of powerful and consistent cutting and stapling force under precise computer-assisted control. Our Intelligent Surgical Instruments are available as disposable, single-patient devices and, in the case of our linear staplers, in an autoclavable multiple-patient format. We intend to migrate our SurgASSIST platform toward a reusable multiple-patient format using disposable reload cartridges.

During the fourth quarter of 2007, we introduced our i60 linear stapler and our iDrive hand-held power and control unit, which are the first of our next-generation products. A key element of our business plan since our inception has been to incorporate the capabilities of our first-generation SurgASSIST System in a new line of self-contained, untethered Intelligent Surgical Instruments. The i60 is a hand-held articulating linear stapler that offers the precise control and powerful, consistent cutting and stapling action of our original tethered instruments in a compact, wireless hand-held form factor, which allows for more flexible manipulation, enhanced dexterity and increased ease of use. During the fourth quarter of 2007, we also obtained 510(k) clearance for our iDrive product, a reusable, self-contained, hand-held power drive and control unit that can be used to power and control our existing suite of linear cutter, right-angle linear cutter, and circular stapler instruments. These next-generation Intelligent Surgical Instruments eliminate the need for the separate power console, control unit and FlexShaft that are required for use of our first-generation products.

We currently focus our marketing and sales efforts on selected surgical procedures in minimally invasive colorectal, bariatric and thoracic surgery. We target those procedures in which we believe the limitations of existing cutting and stapling technology are most acute, where the number of procedures performed is growing rapidly and where clinicians have rapidly recognized the benefits of our Intelligent Surgical Instruments. In the longer term, we intend to promote the use of our SurgASSIST system in many other surgical specialties. As surgical techniques continue to evolve beyond current MIS procedures to even less invasive techniques such as NOTES, we believe our SurgASSIST platform has the potential to become a key enabling technology.

We currently hold 24 issued United States patents, five granted European patents, more than 100 pending United States and foreign patent applications and two licensed patents that cover basic electromechanical and digital control technologies common to all our instruments as well as numerous specific improvements related to particular instruments and procedures.

## **Background**

### *Evolution of surgical technology*

Open surgery has been the most common form of surgery for many decades. Using open surgical techniques, a surgeon generally creates an incision large enough to allow a direct view of the operating field and the insertion of the instruments necessary to manipulate the patient's tissues. The large incisions and significant tissue manipulation involved in open surgery create trauma to the patient, resulting in extended hospitalization and recovery times, increased hospital costs and additional pain and suffering.

Over the past thirty years, surgery has undergone significant change, as technological innovations such as enhanced imaging have led to improved diagnosis and as advanced instruments have facilitated both visualization and surgical access through smaller incisions. These improvements have allowed surgeons to reduce patient trauma, hospital stays and morbidity, while also improving recovery times and cosmetic results. This evolution has both been enabled by, and created opportunities for, the development of new categories of surgical devices.

Minimally invasive surgery replaces the large incision typically required for open surgery with small abdominal openings and ports that provide access to the organs on which the surgeon wishes to operate. The surgeon uses an endoscope to view the anatomy and inserts specialized instruments



through the ports to carry out the procedure. More recently, clinicians and medical device companies have begun working together to develop NOTES, a new, even less invasive, surgical approach that enables surgery to be performed through natural openings such as the mouth or anus instead of the abdominal ports used in MIS.

We believe that realization of the full potential of minimally invasive surgery or the emerging NOTES approach will depend upon the availability of surgical instruments that address the unique challenges of these procedures by offering more advanced capabilities, improved access and flexibility, better ergonomics and greater ease of use than are provided by currently available endomechanical devices.

#### *Limitations of conventional surgical staplers*

The use of mechanical cutting and stapling devices to eliminate tedious and time-consuming hand suturing and to improve the consistency of wound closure and hemostasis has been common in surgery for many years. Endomechanical cutters and staplers are a necessity in minimally invasive surgery, where limited access makes it difficult to achieve effective hemostasis using hand suturing.

The design and utilization of surgical staplers involve a number of challenges. In order to achieve effective wound closure and hemostasis, surgical stapling requires significant and controlled compressive force to provide consistent tissue approximation across the staple line. Staples must also be placed and formed properly. Flexing of the instrument or deflection of the stapling anvil during the stapling operation can result in inconsistent tissue approximation, uneven application of force across the staple line and improper staple formation. These challenges are even more acute in procedures requiring the reconnection, or anastomosis, of a tubular structure such as the colon, where avoidance of tissue damage and preservation of blood supply is critical to prevention of post-operative complications. Achieving these objectives in minimally invasive surgery, which requires the use of slender instruments that can pass through a small diameter port and be operated remotely, creates a unique set of challenges.

Although manually operated staplers have been used in surgery for over a century, we believe there has been little fundamental innovation in conventional surgical stapler design in the last 15 years. Further, we believe that modifications made to conventional surgical staplers to adapt them to the requirements of MIS procedures have created a new set of problems. These limitations affect both clinical outcomes and healthcare costs.

#### **Our Solution**

Our Intelligent Surgical Instruments offer superior consistency, repeatability, compressive force, access to anatomical sites, ergonomics and ease of use compared to conventional endomechanical devices. We believe these attributes of our products result in more consistent and effective wound closure and hemostasis, fewer complications and better clinical outcomes, while also reducing procedure time and cost. As a result, we believe our SurgASSIST system has the potential to become the standard of care in an increasing number of procedures, not only in our current areas of clinical focus of colorectal, bariatric and thoracic surgery, but also in many other surgical specialties.

We believe our SurgASSIST system offers the following key benefits to patients, clinicians, medical institutions and healthcare networks:

- **Powerful and consistent cutting and stapling force** – our SurgASSIST system enables the application of powerful and consistent cutting and stapling force under precise computer-assisted control. Tissue approximation and staple formation are controlled independently, so that compressive force can be optimized for each step. Push button digital control and superior

ergonomics reduce unintended movement during the operation. We believe the result is more consistent staple placement and formation.

- **Enhanced dexterity and flexibility** – our SurgASSIST system is designed specifically to facilitate less invasive surgical techniques, such as MIS and NOTES. The enhanced dexterity, flexibility and ease of use of our Intelligent Surgical Instruments make it easier for clinicians to accurately position our cutting and stapling elements in locations and orientations that maximize access to difficult-to-reach anatomy. Due to their design and our proprietary power transfer technology, our instruments can be operated through an MIS port or natural orifice without sacrificing stability or compressive force. We believe these characteristics have the potential to facilitate wider adoption of MIS and NOTES techniques both by enabling existing procedures to be performed more easily and safely and by broadening the range of indications for which minimally invasive procedures could be performed.
- **Enhanced reliability and ease of use through digital control and communication** – because our SurgASSIST system operates under computer-assisted control, tasks that would require a sequence of discrete manual operations in a conventional stapler are performed automatically, within consistent and repeatable clinically relevant parameters. Our Intelligent Surgical Instruments also provide feedback to the clinician through visual and audio prompts. For example, our SurgASSIST system alerts the surgeon when tissue has been compressed within normal firing range and when the firing sequence has been successfully completed. These capabilities facilitate procedures where visualization is difficult and instruments must be operated remotely.
- **Reduced healthcare costs and improved efficiency of hospital operations** – we offer a reusable, autoclavable linear stapler that can be fired up to 500 times using disposable reload cartridges in a range of staple sizes. We believe that the average cost per procedure of our multiple-use instrument, including the reload cartridge and amortization of the reusable instrument, is generally lower than that of competitive single-use endomechanical devices. In addition, the multiple-use instrument does not need to be disposed of after each procedure, reducing waste disposal costs and conserving materials. We intend to migrate our SurgASSIST platform toward a reusable multiple-patient format using disposable reload cartridges. In addition, we believe the use of our SurgASSIST system can reduce procedure times, permitting more efficient utilization of surgeons' time and operating room resources.

### **Our Target Markets**

Surgical cutting and stapling devices are essential in a wide variety of open and endoscopic surgical procedures. Although we believe our SurgASSIST platform has broad application in many surgical disciplines, we have focused our initial marketing and sales efforts on select procedures in three specialties in which we believe the limitations of existing cutting and stapling technology are most acute, where the number of procedures performed is growing at a rapid rate and where the benefits of our Intelligent Surgical Instruments have been immediately apparent to clinicians.

We have targeted procedures used to treat disease areas that are not only growing through the increase of worldwide population, but also through the expanding incidence of these areas within the existing population. Our current areas of clinical focus include:

- **Colorectal surgery** – according to the American Cancer Society, colorectal cancer is the second leading cause of cancer death in the United States. Colorectal cancer is treated through a surgical procedure known as a colectomy, which is performed using open or laparoscopic techniques to remove diseased tissue and reconnect healthy tissue.

- **Bariatric surgery** – according to the American Obesity Association, nine million Americans are morbidly obese, a condition that leads to premature death and, on average, a 20-year shorter life span. Due to its long-lasting effects, surgical intervention has become the standard of care for morbidly obese patients and is performed through open or laparoscopic techniques to reduce stomach volume. Esophageal surgeries, including the Nissen procedure, are used in the treatment of gastroesophageal reflux disease, or GERD, which affects millions of people in the United States and is associated with significant morbidity. The surgical standard for reconstructing the esophageal sphincter is well established and there is a significant trend to perform this via laparoscopic MIS techniques.
- **Thoracic surgery** – the American Cancer Society predicted that in 2007 there would be about 213,000 new cases of lung cancer in the United States and about 160,000 people would die of this disease. Thoracic surgery is performed through open or laparoscopic techniques and a variety of procedures are used in the treatment of various diseases, including lung cancer and emphysema, through removal or volume reduction of a patient's lungs, as well as ablation of the left atrial appendage of the heart for prevention of cerebral stroke.

### Our Strategy

Our objective is to become a leading worldwide supplier of intelligent surgical instruments used in MIS and NOTES. To attain this objective, we intend to employ the following key strategies:

- **Extend our technology leadership** – we intend to maintain and extend our technology leadership by continuing to enhance the capabilities of our SurgASSIST platform in response to clinician feedback and evolving customer requirements and by expanding our portfolio of proprietary electromechanical and digital technology through focused research and development. For example, the market need for an effective anti-reflux devices is large and well documented, and we have developed a prototype device designed to elongate the esophagus, thus potentially eliminating gastric reflux, as well as devices to enable other procedures for minimally invasive bariatric surgery. Our new PMI Endoscopy group will pursue Intelligent Surgical Instrument applications in the gastrointestinal endoscopy marketplace. In the longer term, we will explore the possibility of incorporating in our SurgASSIST system additional modalities such as digital vision systems, real-time collection of clinical data such as pulse oximetry from the surgical site, and the addition of existing energy-based methods of cutting and wound closure, all introduced through a single port.
- **Increase our installed base of multiple-use devices to grow recurring revenue from sales of reload cartridges** – our i60 hand-held linear stapler utilizes disposable reload cartridges in a standardized format for each firing. Our product development plan is for all future linear stapler products to be multiple-use instruments utilizing disposable reload cartridges. Our objective is to transition users of our first-generation disposable staplers to our multiple-use instruments and to seek opportunities for new placements of our multiple-use instruments in order to maximize the stream of recurring revenue associated with the sale of reload cartridges.
- **Leverage relationships with key institutions and leading clinicians** – we recently organized the MIRAD (Minimally Invasive Resection and Anastomotic Device) Study Group, comprising ten of the world's leading gastrointestinal research labs and have also assembled a group of leading surgeons in the area of gastric surgery, which we call the ESP Study Group. We will continue to devote significant resources to marketing our SurgASSIST platform to key clinicians whom we consider to be leaders in their institutions and fields. We will also work closely with key clinicians and medical institutions on research collaborations to explore new applications of our Intelligent Surgical Instruments. These collaborations provide us with valuable clinician feedback. They can also result in the development of new techniques, taking advantage of the unique

characteristics of our Intelligent Surgical Instruments, that enable existing procedures to be performed more effectively or broaden the range of indications in which established procedures can be applied using MIS techniques.

- **Maintain clinical focus to accelerate adoption of our Intelligent Surgical Instruments** – in the near term, we intend to continue to focus our marketing and sales efforts on a relatively small number of selected surgical specialties and procedures in minimally invasive surgery, with the objective of establishing our Intelligent Surgical Instruments as the standard of care in these procedures. We intend to deepen and expand our relationships with key clinicians in these specialties and procedures. We believe rapid market penetration in these initial areas of clinical focus will broaden market awareness of our SurgASSIST platform and facilitate its adoption in other specialties.
- **Expand our direct sales capabilities worldwide** – enhancing our direct sales capabilities will be critical to our future success. We believe we have established a successful, scalable direct sales model and intend to extend its coverage in selected regions in the United States, Europe and Asia. We will continue to recruit talented sales professionals and clinical specialists who have extensive experience in the clinical requirements of minimally invasive surgery and who have established relationships with key clinicians and institutions. In the near term, we will focus on regions in which top-tier research and medical institutions are located and conduct marketing and training of key clinicians affiliated with those institutions.
- **Enhance operational integration and improve manufacturing efficiencies** – we believe that it is important that we operate as a fully integrated manufacturer of advanced medical devices. We intend to continue to seek opportunities to further integrate our research and development, engineering, manufacturing, marketing, sales and distribution operations. We will also devote substantial resources to improving our procurement and manufacturing processes, upgrading our management information systems and implementing new quality assurance, inventory and cost controls in order to improve the efficiency of our manufacturing operations, maintain product quality, reduce our cost of sales and increase our profitability.

## **Our Technology**

We have developed a number of proprietary technologies that are incorporated in our Intelligent Surgical Instruments. We currently hold 24 issued United States patents, five granted European patents, more than 100 pending United States and foreign patent applications and two licensed patents that cover basic electromechanical and digital control technologies common to all our instruments as well as numerous specific improvements related to particular instruments and procedures. Our core technologies include the following:

### *Power transfer technology*

All of our Intelligent Surgical Instruments use our patented power transfer technology, in which torque generated by electric motors turning at speeds of up to 20,000 revolutions per minute is transferred through two or more rotating metal rods or cables, housed in a rigid or flexible shaft, to actuate the cutting and stapling mechanisms incorporated in each instrument. Because our power transfer technology allows actuating force to be delivered through a rigid or flexible shaft, it also facilitates access to difficult-to-reach anatomy in a way that we believe cannot be duplicated by conventional endomechanical devices, which generally cannot accommodate flexible shafts. Further, our power transfer technology and push button digital control eliminate the need to apply manual force to the handle of the instrument in order to actuate it and reduce the potential for undesired movement of the instrument.

Taking advantage of recent rapid advances in battery, motor and digital control technologies, our next-generation i60 and iDrive products incorporate the same power transfer and micro-robotic technology as are used in our first-generation SurgASSIST system. Motors, drive mechanisms and circuit boards providing functionality equivalent to that contained in our original power console have been miniaturized and integrated into the handpiece, thus eliminating the need for a separate power console, FlexShaft and control unit.

#### *Micro-robotic technology*

Our SurgASSIST system also incorporates our patented micro-robotic technology, in which the speed, direction and sequence of rotation of the power transfer shafts and the selection of gears in highly engineered miniature gearboxes produce the action required for each step of the particular instrument's operation. Push button commands given by the clinician, such as the command to fire the stapler, are interpreted by a microprocessor, which issues a programmed sequence of instructions to the motor control circuits that control the drive motors. Electronic sensors detect the motion of the drive shafts, providing feedback to the microprocessor and enabling the position and operation of the mechanism to be precisely controlled.

This micro-robotic technology, combined with our proprietary power transfer technology, is the key to the ability of our Intelligent Surgical Instruments to apply consistent, precise and powerful compressive force at a remote site within the body. Conventional endomechanical devices, which use an arrangement of pull wires and mechanical linkages to transfer force created by squeezing the instrument handle with one or both hands, cannot match the power or precision of our Intelligent Surgical Instruments. Our Intelligent Surgical Instruments also control the actions of tissue approximation and staple formation independently, so that appropriate clamping force can be used for each operation, whereas conventional staplers rely on the same compressive force generated by manually squeezing the device handle for tissue approximation, cutting and stapling.

#### *Articulation technology*

Building on our proprietary power transfer and micro-robotic technologies, we have developed an innovative method to provide computer-assisted, power-actuated articulation of an endomechanical device. Our i60 linear stapler can both rotate on its rigid shaft and pivot within a range of 90 degrees, enabling it to mimic the articulation of the human wrist. The articulation mechanism is designed to permit the stapler head to be positioned and locked into place through the use of miniaturized gearboxes and fired at any point within its range of motion, all by remote control, without compromising the precision or compressive force of the stapling operation. We believe that it will be feasible to develop devices that combine two or more such articulating joints to provide for additional degrees of freedom, giving surgeons even greater flexibility and access to anatomy. We believe that our articulation technology has the potential to be a key enabling technology in the evolution of MIS and NOTES surgical techniques and further differentiates our SurgASSIST system from competitive endomechanical devices.

#### *Digital intelligence*

Each micro-robotic action of our Intelligent Surgical Instruments is controlled by a microprocessor using our proprietary software and digital control technology. This digital intelligence is a key attribute of our SurgASSIST platform and provides the following benefits not available from conventional endomechanical devices:

- **Computer-controlled precision and consistency** – because the micro-robotic action of our Intelligent Surgical Instruments is computer-controlled, the stapling process is precise to within

hundredths of a millimeter and compressive forces are applied gradually and consistently, providing dependable, repeatable results.

- **Automation** – our Intelligent Surgical Instruments can automatically perform a sequence of steps under software control; as a result, tasks that would require a series of discrete manual operations in a conventional stapler can be accomplished with the push of a button, simplifying the surgeon's task.
- **Digital communication** – digital control enables our Intelligent Surgical Instruments to communicate actively to the clinician; for example, our SurgASSIST system notifies the surgeon by visual and audio alerts when the target tissue has been compressed within normal firing range and when the firing sequence has been successfully completed.
- **Data collection** – our SurgASSIST system can record critical information on each procedure performed, including the type and serial number of the instrument, number of firings, operating parameters and other clinical and administrative data.
- **Rapid upgrade path** – we continually improve and enhance our digital control software and release periodic software upgrades, which can easily be installed to improve the performance of the system and add new functionality, without the need to replace the instruments themselves.

Our patents and patent applications cover key aspects of the digital control technology implemented in our SurgASSIST system, such as the software used to control the micro-robotic action of our Intelligent Surgical Instruments, as well as extensions of our current technology, such as the ability to include multiple SurgASSIST systems in a network to facilitate data collection, billing, patient record keeping and other administrative functions.

#### *Device and procedure-specific improvements*

In addition to the core power transfer, micro-robotic and digital control technologies that are used in all our Intelligent Surgical Instruments, we have developed a number of specific improvements related to particular instruments and procedures, many of which are protected by our patents and patent applications and which we believe provide our products with additional competitive advantages.

#### **Our Products**

Our SurgASSIST surgical platform includes cutting and stapling devices in a variety of sizes and linear, right angle and circular configurations designed for differing surgical needs. In the first-generation configuration of our system, these had to be connected through a flexible shaft, or FlexShaft, to a power console. Our next generation products, beginning with the i60 linear stapler and iDrive system introduced in the fourth quarter of 2007, are self-contained hand-held instruments that do not require a FlexShaft or separate power console. Our Intelligent Surgical Instruments are available as disposable, single-patient devices as well as in a reusable multiple-patient format, using disposable cutting and stapling cartridges.

#### *Our suite of Intelligent Surgical Instruments*

We offer a suite of Intelligent Surgical Instruments to accommodate a range of surgical procedures, in the following categories:

- **Linear staplers** – cutting and stapling devices account for a majority of the instruments we sell. Our new i60 linear stapler is a hand-held, untethered, reloadable, multiple-patient linear cutter and stapler. The i60 offers the precise control and powerful, consistent cutting and stapling action of our first-generation tethered linear staplers in a compact, hand-held form factor, which allows for even more flexible manipulation, enhanced dexterity and increased ease of use.

Motors, drive mechanisms and circuit boards providing functionality equivalent to that contained in our original power console have been miniaturized and integrated into the handpiece. This eliminates the need for a separate power console, FlexShaft and control unit. The i60 instrument communicates wirelessly with a newly designed console to provide for operator feedback and data collection

We also offer a reloadable single-patient linear stapler, typically used in open surgical procedures, as well as a reloadable multiple-patient linear stapler, intended for use in MIS procedures. These can be used either with our original power console and FlexShaft configuration, or with our new self-contained handheld iDrive power and control unit.

Our multiple-patient linear staplers can be autoclaved for multiple-patient use, and the instrument is capable of firing our reloadable staple cartridges up to 500 times before replacement. Unlike many conventional staplers, our reloadable multiple-patient linear staplers are designed to transect compressed tissue from the farthest, or distal, end of the instrument to the nearest, or proximal, end, reducing the likelihood of pinching tissue in the jaws of the instrument or squeezing it out of the distal end, and providing even tissue approximation and accurate staple placement and formation.

- **Right angle linear cutters** – we offer two types of disposable single-use right angle linear cutters, which are designed to enable clinicians to access difficult-to-reach areas of anatomy, such as in low anterior colorectal resections. We also offer a right angle linear cutter designed specifically for the vascular market, which features three rows of staggered staples on either side of the cut line. The proprietary parallel jaw design of our right angle linear cutter, with its guillotine surgical blade, enables true parallel closure for consistent staple formation and control. In addition, staples in multiple sizes can be accommodated in a single instrument, allowing the clinician to select the staple height during the procedure without removing the stapler. These instruments can be used either with our original power console and FlexShaft configuration, or with our new self-contained handheld iDrive power and control unit
- **Circular staplers** – we offer two lines of disposable single-use circular staplers. Each model creates a double staggered row of titanium staples in a circular pattern to facilitate tissue resection and anastomosis. Our PCS 21, which we believe is the world's first stapling device designed for per-oral introduction, is used to perform NOTES procedures, primarily in gastric bypass applications. Our PCS 29 is designed primarily for laparoscopic colorectal resection. Our circular staplers have been optimized to provide superior access and control in MIS procedures. For example, we designed a proprietary latching system to enable easier use in the narrow pelvis in a procedure such as a laparoscopic colon resection. These instruments can also be used either with our original power console and FlexShaft configuration, or with our new self-contained handheld iDrive power and control unit.

#### *Ancillary components (used with first-generation Intelligent Surgical Instruments)*

The following ancillary components are also available as part of our first-generation SurgASSIST platform:

- **Power console** – a mobile unit that can be moved from one operating room to another; it houses communications and control circuitry, an operator display and the drive motors that provide the system's actuating power.
- **FlexShaft** – a flexible shaft, two meters in length, that provides for power transmission and acts as a data conduit between the Intelligent Surgical Instrument and the power console; available in steerable and non-steerable configurations.

- **Remote control unit** – a hand-held wired or wireless controller that enables push button digital control of the instrument. Our reloadable multiple-patient linear stapler integrates the controls in the handpiece, eliminating the need for a separate control unit.

Our Intelligent Surgical Instruments can be used interchangeably with a single iDrive power and control unit, or with a single power console and FlexShaft. The surgeon operates the system by connecting the selected Intelligent Surgical Instrument to the iDrive or to the power console via a FlexShaft. The computer in the iDrive or power console automatically identifies the type and serial number of the Intelligent Surgical Instrument that is attached, calibrates the system to the specific instrument and confirms that the system is operating normally and is ready for use. Information gathered by the computer is communicated to the surgeon both by a visual display and through voice prompts.

The surgeon then maneuvers the Intelligent Surgical Instrument into position. Upon the surgeon's push-button commands, the instrument's digital controls prepare the instrument for firing, apply graduated compressive force to achieve the desired degree of tissue approximation and fire the stapler. Upon firing, a computer-controlled firing sequence occurs in which staggered rows of titanium staples are laid down on either side of the surgical blade and the blade transects the tissue between the rows of staples. Throughout the process, the SurgASSIST system provides feedback through visual and audio prompts, notifying the surgeon when tissue is within the target firing range for the selected staple height, when the system is ready for firing and when the firing sequence has been completed.

Many of our targeted surgical procedures require the use of multiple firings of a single instrument or the use of multiple instruments. For instance, during the course of a gastric bypass procedure for treating morbidly obese patients, known as stomach stapling, a surgeon may use two or more Intelligent Surgical Instruments, each of which may be fired multiple times.

#### *Future Intelligent Surgical Instruments*

We plan to introduce a new line of instruments designed specifically for introduction through a natural orifice, for use in NOTES. In December 2006, we obtained 510(k) clearance from the FDA to market our new natural orifice linear cutter, or NOLC. This Intelligent Surgical Instrument, which will combine a 12mm linear stapling device and a flexible shaft, is designed specifically to facilitate NOTES, by enabling surgeons to perform procedures through the gastrointestinal tract without cutting or puncturing the abdominal wall. We expect to launch our NOLC product in the first half of 2008.

We also intend to launch a number of extensions of our line of iSeries linear staplers, including our i60RB4 linear stapler for cardiovascular indications, our i45 linear stapler in blue and green staple lengths, and our i45V linear stapler for vascular applications. The i60RB4 is a version of our new i60 hand-held linear stapler designed specifically for use in cardiovascular surgery for the occlusion of the heart's left atrial appendage. Our i45 linear stapler is identical to the i60 with the exception of the length of the staple line; the shorter length provides for access in small tight anatomical spaces such as the thorax (for lung resections and lung transplants) and the deep pelvis for colon and rectal surgery. Our i45V is our first vascular Intelligent Surgical Instrument, intended for use on pulmonary arteries and veins and other vascular applications through the circulatory system. We are in the process of applying to the FDA for 510(k) clearances for our i60RB4 and i45V instruments.

We have also developed a prototype device designed to elongate the esophagus, thus potentially eliminating gastric reflux, and are working on devices to enable other procedures for minimally invasive bariatric surgery.

In the longer term, we intend to explore the possibility of incorporating additional modalities into our Intelligent Surgical Instruments, such as digital optical systems, real-time collection of clinical data such as pulse oximetry from the surgical site and existing energy-based methods of cutting and



coagulating at the wound site. Our goal is to integrate these additional modalities with our SurgASSIST system's existing capabilities in Intelligent Surgical Instruments that could be introduced through a single MIS port.

Many of our new products and technologies will require FDA clearance of a 510(k), or may require FDA approval of a PMA. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. The FDA may also refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products.

### **Sales, Marketing and Distribution**

We sell our Intelligent Surgical Instruments through our direct sales force in the United States and through a combination of direct sales personnel and distributors elsewhere in Europe and Japan. As of March 28, 2009, our U.S. direct sales organization included 36 account sales representatives, organized in ten regions, each headed by a regional manager. Our sales force in Europe consisted of a regional manager, based at our wholly-owned subsidiary in Hamburg, Germany, managing a team of 9 sales associates in Germany, and a sales manager in France with a team of seven associates. Our sales force in Japan consisted of a general manager and four sales associates.

Account sales representatives are responsible for selling our products and working with customers on training and supporting product use. Our account sales representatives are typically present in the operating room with our surgeon customers, facilitating their understanding of our SurgASSIST technology and the use of our Intelligent Surgical Instruments. Having our sales representatives present when our products are being used also provides us with immediate feedback and understanding of our customers' needs in real-world conditions. Our sales representatives also seek to develop contacts and relationships at the nursing, staff and hospital administration levels.

Our direct sales force also provides support and service to our customers. In addition, we maintain a staff of customer service personnel in our Langhorne, Pennsylvania facility that is available by phone to our customers to answer questions. Our sales representatives receive two weeks of intensive training at our Langhorne facility on surgical anatomy, procedures, stapling techniques, the function and use of the SurgASSIST system and all its components, troubleshooting and selling skills. In addition, they fire all of our products in a lab under the guidance of experienced surgeons. At the completion of this training, they are tested prior to receiving one week of field training with an experienced field trainer. They are supported closely during their first six months on the job by their regional manager through regular field visits.

We believe we have established a successful, scalable direct sales model and intend to extend its coverage in selected regions in the United States, Europe and Asia. We will continue to recruit talented sales professionals and clinical specialists who have extensive experience in the clinical requirements of minimally invasive surgery and who have established relationships with key clinicians and institutions. In the near term, we will focus on regions in which top-tier research and medical institutions are located and in which we currently have no direct sales coverage, and will conduct intensive marketing and training of key clinicians affiliated with those institutions.

Our relationships with leading physicians in colorectal, thoracic and bariatric medicine are also an important component of our selling efforts. These relationships are typically built around research collaborations that enable us to better understand and articulate to other clinicians the most useful features and benefits of our products, and to develop new solutions to challenges in minimally invasive surgery. These relationships also provide a framework for peer-to-peer training of other clinicians by respected leaders in their fields who are experienced in the use of our Intelligent Surgical Instruments.

We currently make our i60 linear stapler handpieces and iDrive hand held drive and control units available to institutions at no charge. Similarly, in 2007 we instituted a program whereby we provide our reusable PLC 60 instruments or FlexShafts to customers at no cost, in exchange for a commitment by the customer to purchase a minimum number of reload cartridges at a higher unit price. We believe these practices have helped us to seed the market for our SurgASSIST system, have encouraged clinicians and institutions to use our Intelligent Surgical Instruments and have accelerated their adoption. For products offered for sale, such as reload cartridges, we may offer discounts from our list prices, typically ranging from 5% to 10%, based on minimum purchase commitments and other considerations.

### **Research and Development**

As of March 28, 2008, our research and development organization consisted of 19 persons, located in our headquarters facility in Langhorne, Pennsylvania, and in our research and development facility in Shelton, Connecticut. Our research and development expenses were \$6.2 million in 2007, \$4.7 million in 2006 and \$5.5 million in 2005.

### **Manufacturing and Supplier Relationships**

We conduct our manufacturing operations at our main facility in Langhorne, Pennsylvania. Our manufacturing operations currently consist primarily of assembly of components and sub-assemblies that are fabricated to our specifications by external suppliers. We conduct quality assurance testing and inspection of purchased components, perform final assembly and quality assurance testing, and package and ship our products.

The principal components used in the manufacture of our products are molded plastic parts, machined metal parts, mechanical sub-assemblies, electronic circuit boards, switches and wiring. We purchase the components and sub-assemblies required for manufacturing our SurgASSIST system from third-party suppliers and contract manufacturers. We qualify these vendors through stringent evaluation and monitoring of their performance over time. We rely on sole source suppliers for certain components, such as electronic circuit boards, and certain services, such as sterilization of finished goods. We do not have long-term contracts with most of our suppliers. We have a long term contract with our printed circuit board and motor gear assembly suppliers, and we are actively seeking to establish long-term supply arrangements with other key suppliers. It would be difficult for us to quickly establish additional or replacement suppliers for certain components or materials, due to both the complex nature of the manufacturing processes employed by our suppliers and the time and effort that may be required to validate alternative suppliers. Any significant supply interruption or capacity constraints affecting our facilities or those of our suppliers would adversely affect our ability to manufacture and distribute our products.

Our manufacturing operations and those of the third-party manufacturers we use are subject to extensive regulation by the FDA under its quality systems regulations, or QSRs, good manufacturing practice regulations, and regulations promulgated by the European Union and Japan. Our facility is FDA registered and ISO 9001:2000 certified. Our products are approved for sale in the European Union, having obtained "CE," or European Compliance, marking.

Our facility and the facilities of the third-party manufacturers we use are subject to periodic, unannounced inspections by regulatory authorities, including the FDA and other governmental agencies. From February 13 to April 26, 2007, the FDA conducted an inspection of our facility in Langhorne, Pennsylvania. A Notice of Inspectional Observations, or Form 483, was provided to us at the conclusion of the inspection. In the FDA's Form 483, 24 inspectional observations were identified, including the failure to properly process customer complaints, failure to submit to the FDA medical device reports or to submit them within regulatory timeframes, and the lack of reporting a field action.

We prepared and submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations. We were last inspected by our E.U. Notified Body in July 2005. Three minor deficiencies were cited and no response was required. We expect to be inspected by the FDA and the E.U. notified body again in the future. If the FDA or the E.U. finds significant shortcomings, or if the FDA is not satisfied with our responses to the 2007 inspection, we could be subject to sanctions, including fines, recalls or requirements to halt manufacturing and shipments of affected products.

Our business plans require that we achieve continued improvements in our manufacturing operations and in our cost of sales compared with those we have recently experienced. We believe that increasing the automation of our assembly operations will be critical in achieving this objective. We have also devoted, and plan to continue to devote, substantial resources to improving our procurement and manufacturing processes, upgrading our management information systems, and implementing new quality assurance, inventory and cost controls in order to improve the efficiency of our manufacturing operations, maintain product quality, reduce our cost of sales and increase our profitability.

We also intend to increase the integration of our manufacturing operations. For example, we recently acquired the automated equipment necessary to enable us to assemble the reload cartridges used in our multiple-use linear staplers. We expect this system to be operational during the second quarter of 2008. Currently, the assembly of reloads for some of our products is performed manually by us, and for other products is outsourced to a contract manufacturer. We believe that operating as an integrated manufacturer will enable us to better control the quality, cost and supply of our products and to more rapidly develop, prototype and commercialize new products.

We have also undertaken a number of programs intended to improve the efficiency and reliability of our supply chain and manufacturing operations. These initiatives include:

- supplier quality management and incoming component inspection procedures;
- improved management controls, including a new standard cost system; and
- improved management of finished goods inventory levels.

These initiatives are still in the process of being implemented. We will need to complete these initiatives and to make additional improvements in the efficiency and reliability of our supply chain and manufacturing activities in order to meet existing and anticipated demand for our products in a timely manner and at a cost that enables us to operate profitably.

## **Competition**

The market for endomechanical cutting and stapling devices is intensely competitive and dominated by a small number of large, well-known companies, principally United States Surgical Corporation, a division of Covidien Ltd., or Covidien (formerly known as Tyco Healthcare), and Ethicon Endo-Surgery, a Johnson & Johnson company.

We believe that the principal competitive factors in the market for endomechanical cutting and stapling devices include:

- efficacy and consistency of wound closure and hemostasis;
- ability to provide access to difficult-to-reach anatomy;
- ease of use, visibility for the surgeon and control over the device;
- innovation and the number and variety of addressable surgical applications;
- product quality and reliability;

- quality of customer support and service, including technical assistance, product information, reimbursement assistance and handling of complaints;
- brand reputation and financial resources and stability of supplier; and
- cost.

Many of our competitors have significantly greater financial and human resources than we do, have established relationships with healthcare professionals, customers and third-party payors, and have long-term contracts with group purchasing organizations in the United States, such as Premier Hospital Supply, Inc. and Novation, LLC, of which many hospitals in the United States are members. In addition many of our competitors have established distributor networks, greater resources for product development, sales and marketing, additional lines of products and the ability to offer financial incentives such as rebates, bundled products or discounts on other product lines that we cannot provide.

We have encountered and expect to continue to encounter potential hospital customers which, due to existing relationships or beneficial pricing or other financial arrangements with our competitors, are committed to, or prefer the products offered by, these competitors. We expect that competitive pressures may result in price reductions and reduced margins over time for our products. Our products could also be rendered obsolete or uneconomical by technological advances developed by one or more of our competitors.

### **Intellectual Property**

We believe that in order to maintain a competitive advantage in the marketplace, we must develop and maintain the proprietary aspects of our technologies. We rely on a combination of patent, trademark, trade secret, copyright and other intellectual property rights and measures to aggressively protect our intellectual property.

We rely on other forms of intellectual property, including trade secrets and know-how, to develop and maintain our competitive position. We require our employees and consultants to execute confidentiality agreements in connection with their employment or consulting relationships with us. We also require our employees and consultants who work on our products to agree to disclose and assign to us all inventions conceived during the term of their employment, while using our property or which relate to our business. Despite measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary. In addition, our competitors may independently develop similar technologies.

We seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our technology, inventions and improvements that are important to the development of our business. As of December 31, 2007, we hold 24 issued United States patents, five granted European patents, more than 100 pending United States and foreign patent applications filed in select international markets and two licensed patents. Our issued patents expire at various dates beginning in 2019.

Finally, we believe that certain of our trademarks are valuable assets that are important to the marketing of our products. Many of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate.

Patent applications in the United States and in foreign countries are maintained in secrecy for a period of time after filing, which results in a delay between the actual discoveries and the filing of related patent applications and the time when discoveries are published in scientific and patent literature. Patents issued and patent applications filed relating to medical devices are numerous, and there can be no assurance that current and potential competitors and other third parties have not filed

or in the future will not file applications for, or have not received or in the future will not receive, patents or obtain additional proprietary rights relating to products, devices or processes used or proposed to be used by us. We are aware of patents issued to third parties that contain subject matter related to our technology. We believe that the technologies we employ in our products and systems do not infringe the valid claims of any such patents. There can be no assurance, however, that third parties will not seek to assert that our devices and systems infringe their patents or seek to expand their patent claims to cover aspects of our products and systems.

The medical device industry in general has been characterized by substantial litigation regarding patents and other intellectual property rights. Any such claims, regardless of their merit, could be time-consuming and expensive to respond to and could divert our technical and management personnel. We may be involved in litigation to defend against claims of infringement by other patent holders, to enforce patents issued to us, or to protect our trade secrets. If any relevant claims of third-party patents are upheld as valid and enforceable in any litigation or administrative proceeding, we could be prevented from practicing the subject matter claimed in such patents, or would be required to obtain licenses from the patent owners of each such patent, or to redesign our products, devices or processes to avoid infringement. There can be no assurance that such licenses would be available or, if available, would be available on terms acceptable to us or that we would be successful in any attempt to redesign our products or processes to avoid infringement. Accordingly, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products.

We intend to vigorously protect and defend our intellectual property. Costly and time-consuming litigation brought by us may be necessary to enforce patents issued to us, to protect trade secrets or know-how owned by us or to determine the enforceability, scope and validity of the proprietary rights of others.

#### **Government Regulation**

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the Federal Food, Drug, and Cosmetic Act, or the FDCA, as implemented and enforced by the U.S. Food and Drug Administration, or the FDA. Certain of our products sold in the United States require FDA clearance to market under Section 510(k) of the FDCA. Foreign countries may require similar or more onerous approvals to manufacture or market these products.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the Federal Trade Commission and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products of other companies have been the subject of enforcement action brought under healthcare reimbursement laws and consumer protection statutes. In addition, under the federal Lanham Act and similar state laws, competitors and others can initiate litigation relating to advertising claims. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

In addition, other government authorities influence the success of our business, including the availability of adequate reimbursement from third-party payors, including government programs such as Medicare and Medicaid. Medicare and Medicaid reimbursement policies can also influence corresponding policies of private insurers and managed care providers, which can further affect our business.

Unless an exemption applies, before we can commercially distribute medical devices in the United States, we must obtain, depending on the type of device, either prior 510(k) clearance or premarket approval, or PMA, from the FDA. Each of our currently available Intelligent Surgical Instruments is a 510(k)-cleared device. To obtain 510(k) clearance, we must submit a notification to the FDA demonstrating that our proposed device is substantially equivalent to a predicate device (i.e., a device that was in commercial distribution before May 28, 1976, a device that has been reclassified from Class III to Class I or Class II, or a 510(k)-cleared device). The FDA's 510(k) clearance process generally takes from three to 12 months from the date the application is submitted but can take significantly longer. If the FDA determines that the device or its intended use is not substantially equivalent to a predicate device, the device is automatically placed into Class III, requiring the submission of a PMA. In addition, any modification to a 510(k)-cleared device that would constitute a major change in its intended use, or any change that could significantly affect the safety or effectiveness of the device, requires a new 510(k) clearance and may even, in some circumstances, require a PMA, if the change raises complex or novel scientific issues or the product has a new intended use.

The FDA requires every manufacturer to make the determination regarding the need for a new 510(k) submission in the first instance, but the FDA may review any manufacturer's decision. If the FDA disagrees with a manufacturer's determination, the FDA can require the manufacturer to cease marketing and/or recall the device until 510(k) clearance or PMA is obtained. If the FDA requires us to seek 510(k) clearance or PMAs or supplements for any modifications, we may be required to cease marketing and/or recall the modified device, if already in distribution, until 510(k) clearance or PMA or PMA supplement approval is obtained and we could be subject to significant regulatory fines or penalties. Furthermore, our products could be subject to voluntary recall if we or the FDA determine, for any reason, that our products pose a risk of injury or are otherwise defective. Moreover, the FDA can order a mandatory recall if there is a reasonable probability that our device would cause serious adverse health consequences or death. There is no guarantee that the FDA will grant 510(k) clearance, if required, for any of our future products and failure to obtain necessary clearances for our future products would adversely affect our ability to grow our business. Delays in receipt or failure to receive required clearances, the loss of previously received clearances, or the failure to comply with existing or future regulatory requirements could reduce our sales, profitability and future growth prospects.

We have modified our devices to improve quality and customer satisfaction since the products received their FDA clearances. Typical modifications included changes to machined-part dimensions, changes to materials of construction and changes to software programs. We believe that these modifications generally did not require new 510(k) clearances because they could not significantly affect the safety or effectiveness of the products and did not represent a major change to the intended use of the products. In those cases where we concluded that a new 510(k) clearance was required, we applied for and obtained the new clearance. We based each determination on decision criteria in FDA guidance documents and our understanding of how FDA and industry interpret such guidance documents. If the FDA were to disagree with any of our determinations that changes did not require a new 510(k), it could require us to cease marketing and distribution of, and/or, recall the modified device until 510(k) clearance or PMA approval is obtained. Also, in these circumstances, we could be subject to significant regulatory actions, including, but not limited to, fines, penalties and warning letters.

Devices that cannot be cleared through the 510(k) process require the submission of a PMA. The PMA process is much more time consuming and demanding than the 510(k) notification process. A PMA must be supported by extensive data, including but not limited to data obtained from preclinical or clinical studies or relating to manufacturing and labeling, to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. After a PMA application is submitted, the FDA's in-depth review of the information generally takes between one and three years and may take significantly longer.

Clinical trials are generally required to support a PMA application and are sometimes required for 510(k) clearance. None of our products currently is, or has been, the subject of a clinical trial. Clinical trials are subject to extensive monitoring, recordkeeping and reporting requirements. Clinical trials must be conducted under the oversight of an institutional review board, or IRB, for the relevant clinical trial sites and must comply with FDA regulations, including but not limited to those relating to good clinical practices.

After a device is placed on the market, numerous regulatory requirements continue to apply. These include, but are not limited to,:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulation, or QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance by the FDA of product modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices;
- approval by the FDA of product modifications that affect the safety or effectiveness of our products, if any, that are approved by the FDA;
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device; and
- notices of correction or removal and recall regulations.

We have registered our facility with the FDA as a medical device manufacturer. We are subject to announced and unannounced inspections by the FDA to determine our compliance with the QSR and other regulations and these inspections may include the manufacturing facilities of our suppliers. Between May 2002 and June 2005, the FDA conducted three inspections of our facilities. Each of those inspections resulted in the issuance of a Notice of Inspectional Observations, or Form 483. Certain observations regarding our processes to handle customer complaints, submit medical device reports, initiate corrective and preventive actions and to conduct internal quality audits were identified by the FDA as areas of possible non-compliance with FDA regulations. For each of those Form 483s issued by the FDA, we submitted a response which identified our proposed corrective action plans to address these inspectional observations. In each case, the FDA issued an Establishment Inspection Report, or EIR, which officially closed the FDA's inspection. From February 13 to April 26, 2007, the FDA conducted an additional inspection of our facility in Langhorne, Pennsylvania. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, 24 inspectional observations were identified, including the failure to properly process customer complaints, failure to submit to the FDA medical device reports or to submit them within regulatory timeframes, and the lack of reporting a field action. Certain of the FDA's inspectional observations are similar to observations identified in the prior 483s issued to us. We prepared and submitted a response to the

FDA, which included our proposed corrective actions to address the FDA's observations. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of the current inspectional observations to the previous observations.

The MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. The FDA can take enforcement action against us if we fail to report such adverse events on a timely basis or at all. We have initiated certain voluntary recalls involving products that have been distributed to our customers, and may take additional such actions in the future. We believe that certain of those recalls do not require notification to the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

Many of our products are cleared by the FDA for use in various surgical applications. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific procedures until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

International sales of medical devices are subject to foreign governmental regulations which vary substantially from country to country. Modifications to our approved products require a new regulatory submission in all major markets. The time required to obtain certification or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ.

### **Third Party Coverage and Reimbursement**

Sales of medical products are increasingly dependent in part on the availability of reimbursement from third-party payors such as government and private insurance plans. In the United States, as well as in foreign countries, government-funded or private insurance programs, commonly known as third-party payors, pay the cost of a significant portion of a patient's medical expenses. Successful sales of our products will depend on the availability of adequate reimbursement from third-party payors. No uniform policy of coverage or reimbursement for medical technology exists among all these payors. Therefore, coverage and reimbursement can differ significantly from payor to payor.

Hospitals and other healthcare providers that purchase medical devices, such as the ones that we manufacture, rely on third-party payors to pay for all or part of the costs and fees associated with the procedures performed with these devices. The existence of adequate reimbursement for the procedures performed with our products by government and private insurance plans are central to acceptance of our current and future products. We may be unable to sell our products on a profitable basis if third-party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels.



Many private payors use coverage decisions and payment amounts determined by the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, as guidelines in setting their reimbursement policies. Future action by CMS or other government agencies may diminish payments to physicians, outpatient centers and hospitals. Those private payors that do not follow the Medicare guidelines may adopt different reimbursement policies for procedures performed with our products. For some governmental programs, such as Medicaid, reimbursement differs from state to state, and some state Medicaid programs may not pay for the procedures performed with our products in an adequate amount, if at all.

Even if a device has received approval or clearance for marketing by the FDA, there is no assurance that Medicare will cover the device and related services. In some cases, CMS may place certain restrictions on the circumstances in which coverage will be available. In making such coverage determinations, CMS considers, among other things, peer-reviewed publications concerning the effectiveness of the technology, the opinions of medical specialty societies, input from the FDA, the National Institutes of Health, and other government agencies. We cannot assure you that once our products are commercially available, they will be covered by Medicare and other third-party payors. Limited coverage of our products could have a material adverse effect on our business, financial condition and results of operations.

In general, Medicare makes a predetermined, fixed payment amount for its beneficiaries receiving covered inpatient services in acute care hospitals. This payment methodology is part of the inpatient prospective payment system, or IPPS. For acute care hospitals, under IPPS, payment for an inpatient stay is based on diagnosis-related groups, or DRGs, which include reimbursement for all covered medical services and medical products that are provided during a hospital stay. Additionally, a relative weight is calculated for each individual DRG which represents the average resources required to care for cases in that particular DRG relative to the average resources required to treat cases in all DRGs. Generally, DRG relative weights are adjusted annually to reflect changes in medical practice in a budget neutral manner.

For classification of physician services, the American Medical Association, referred to as the AMA, has developed a coding system known as the Current Procedural Terminology, or CPT. CPT codes are established by the AMA and adopted by the Medicare program in the Healthcare Common Procedure Coding System, to describe and develop payment amounts for physician services. Physician services are reimbursed by Medicare based on a physician fee schedule whereby payment is based generally on the number of "relative value units" assigned by CMS to the service furnished by the physician. CPT codes are used by many other third-party payors in addition to Medicare. Failure by physicians to receive what they consider to be adequate reimbursement for procedures in which our products are used could have a material adverse effect on our business, financial condition and results of operations.

Our international success will depend upon the availability of reimbursement within prevailing foreign healthcare payment systems. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government-sponsored healthcare and private insurance. Several countries have reimbursement codes that apply to the use of our products. These countries include Germany, Belgium, the Netherlands and Japan. The rates vary by country and vary with respect to products and procedures.

All third-party reimbursement programs, whether government funded or insured commercially, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, second opinions required prior to major surgery, careful review of bills, encouragement of healthier lifestyles and exploration of more cost-effective methods of delivering healthcare. These types of programs and legislative changes to reimbursement policies could potentially limit the amount which healthcare providers may be willing to pay for medical devices.

As the portion of the United States population over age 65 and eligible for Medicare continues to grow we may be more vulnerable to reimbursement limitations imposed by CMS. Furthermore, the healthcare industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control healthcare costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that the procedures performed with our products will be adequately reimbursed.

### **Fraud and Abuse Laws**

The costs of human healthcare have been and continue to be a subject of study, investigation and regulation by governmental agencies and legislative bodies around the world. In the United States, attention has been focused on drug and device prices and profits and programs that encourage doctors to write prescriptions for particular drugs or recommend, use or purchase particular medical devices. Payors have become a more potent force in the market place and increased attention is being paid to drug and medical device pricing, appropriate drug and medical device utilization and the quality and costs of health care.

A variety of Federal and state laws apply to the sale, marketing and promotion of medical devices that are paid for, directly or indirectly, by Federal or state healthcare programs, such as Medicare, Medicaid and TRICARE. The restrictions imposed by these laws are in addition to those imposed by the FDA, FTC and corresponding state agencies. Some of these laws significantly restrict or prohibit certain types of medical device manufacturers. Violation of these laws can result in significant criminal, civil, and administrative penalties, including imprisonment of individuals, fines and penalties and exclusion or debarment from Federal and state healthcare and other programs. Many private health insurance companies also prohibit payment to entities that have been sanctioned, excluded, or debarred by Federal agencies.

*Anti-kickback statute.* The Federal anti-kickback statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for or recommending of a good or service, for which payment may be made in whole or part under a Federal healthcare program such as the Medicare and Medicaid programs. The definition of "remuneration" has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under Federal healthcare programs, the statute has been violated. Penalties for violations include criminal penalties and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other Federal healthcare programs. In addition, some kickback allegations have been claimed to violate the Federal False Claims Act, discussed in more detail below.

The Federal anti-kickback statute is broad and prohibits many types of arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of the Department of Health and Human Services, or OIG, has issued a series of regulations, known as the "safe harbors." These safe harbors set forth provisions that, if all their applicable requirements are met, will assure healthcare providers and other parties to a transaction or arrangement that they will not be prosecuted under the federal anti-kickback statute. We seek where possible to comply with these safe harbors. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy an applicable safe harbor may result in increased scrutiny or enforcement action by government enforcement authorities such as the OIG or the U.S. Department of Justice. Many states have adopted laws similar to the

Federal anti-kickback statute. Some of these state prohibitions are broader than the Federal statute, and apply to the referral of patients and recommendations for healthcare items or services reimbursed by any source, not only government-funded programs.

***False claims laws.*** Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the Federal government or knowingly making, or causing to be made, a false statement in order to have a false claim paid. The Federal government's interpretation of the scope of the law has in recent years grown increasingly broad. Most states also have statutes or regulations similar to the Federal false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these Federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Several device manufacturers have been prosecuted under the false claims laws for allegedly providing free product to physician customers with the expectation that the physician customers would bill Federal programs for the product.

***Fraud on a health benefit plan and false statements.*** The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created a new Federal healthcare fraud statute that prohibits knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from government-sponsored programs. Among other things, HIPAA also imposes new criminal penalties for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services, along with theft or embezzlement in connection with a healthcare benefits program and willful obstruction of a criminal investigation involving a Federal healthcare offense. Violations may result in fines or imprisonment.

We engage in a variety of activities that are of the general character that are subject to these laws and that have come under particular scrutiny in recent years by federal and state regulators and law enforcement entities. These activities have included consulting arrangements with surgeons, grants for training and other education, grants for research, and other interactions with physicians. We believe that our practices are not in violation of the Federal anti-kickback statute, false claims laws, HIPAA or state equivalents, but we cannot assure you that enforcement authorities will not take action against us and, if such action were successful, we could be required to pay significant fines and penalties and change our marketing practices. Such enforcement could have a significant adverse effect on our ability to operate.

## **Employees**

As of March 28, 2008, we had 177 employees, including 30 in manufacturing, 82 in sales and marketing, 15 in clinical, regulatory and quality assurance, 15 in general and administrative, 19 in research and development and 16 in operations. We believe that our future success will depend upon our continued ability to attract, hire and retain qualified personnel. We occasionally employ independent contractors, consultants and temporary employees to support our operations. None of our employees is represented by a labor union or party to a collective bargaining agreement, and we believe our employee relations are good.

**Item 1A. Risk Factors.**

**Risks Related to Our Business**

**We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.**

We are a company with a limited operating history and have sustained net losses since our inception, including a net loss of \$36.8 million for the year ended December 31, 2007 and a net loss of \$28.3 million for the year ended December 31, 2006. We had an accumulated deficit of \$173.9 million at December 31, 2007. We expect to continue to incur significant operating losses at least through 2008, as we invest in the development of our business. Our losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

**We are dependent on the success of our SurgASSIST platform and, in particular, of the next generation wireless handheld technology incorporated in our recently released i60 and iDrive products, and we cannot be certain that our technology and our products will achieve the broad market acceptance necessary to develop a sustainable, profitable business.**

Historically, most of our revenue has been derived from the sale of our single-patient, disposable Intelligent Surgical Instruments and, to a lesser extent, from the sale of reload cartridges for our reusable Intelligent Surgical Instruments. We expect that sales of our first generation products will continue to account for most of our sales for at least the next six months. However, we expect that, as our installed base of reusable, multiple-patient Intelligent Surgical Instruments grows and the number of firings of our instruments increases, sales of reload cartridges will become the largest component of our total sales. It is difficult to predict the penetration, future growth rate or size of the market for our SurgASSIST platform or the rate at which our installed base of instruments will be fired.

The commercial success of our various Intelligent Surgical Instruments will require broad acceptance of the SurgASSIST platform by the surgeons who specialize in the procedures we target, a limited number of whom may be able to influence device selection and purchasing decisions. If the concept of computer-assisted power-actuated devices for tissue manipulation, cutting and stapling is not broadly accepted and perceived as having significant advantages over manually-actuated devices, then we will not meet our business objectives. Broad acceptance of our SurgASSIST platform will require a determination by hospitals and surgeons that our products are safe, cost-effective and represent acceptable methods of treatment. In addition, certain components of our SurgASSIST platform in its current configuration may be considered to be capital purchases that require administrative procedures and approvals from senior hospital management, the result of which can be an extended sales cycle requiring multiple individuals to believe in the advantages of our products. We cannot assure that our existing relationships and arrangements with hospitals and surgeons can be maintained or that new relationships will be established in support of our products. In addition, our competitors may develop new technology for tissue manipulation, cutting and stapling that is more attractive to surgeons and hospitals. If surgeons do not consider our products to be suitable for application in the procedures we are targeting and an improvement over the use of competing products, our business goals will not be realized.

**The success of our business is dependent on our ability to develop new and innovative products and to enhance our existing products. We experienced significant delays in new product introduction in 2006 and 2007, and if we do not achieve our current development goals in the time frames we expect, the commercialization of our new products may be delayed and, as a result, our operations may be adversely affected.**

The success of our business is dependent on our ability to develop new products, to introduce enhancements to our existing products and to develop these new technologies within targeted time

frames. These target estimates are based on a variety of assumptions. The actual timing of these milestones can vary dramatically compared to our estimates for reasons that may or may not be within our control. For example, the commercial release of our PLC 60 linear stapler in 2006 was delayed almost nine months due to product design flaws and supply chain problems, and our ability to generate revenue from the PLC 60 staplers that we placed in hospitals beginning in December 2006 was adversely affected due to the unavailability in 2007 of certain reload cartridges for the device.

Similarly, our ability to generate revenue from the new i60 liner stapler that we introduced in September 2007 has been adversely affected by the unavailability of green reload cartridges for the device and by problems with the initial quality of units delivered to customers and other issues. Design and materials engineering problems affecting a key component of the green reloads, which is manufactured for us by a third party, have required us to redesign the part. We currently expect the redesigned green reloads to be available in commercial quantities in the second quarter of 2008. Some early users of our i60 instrument have experienced difficulties, such as problems in consistently operating its articulation feature and in properly seating reload cartridges. Although these difficulties may in part be attributable to inadequate training or incorrect technique, they have led in some cases to a negative perception of product quality. Additionally, training of our sales force and the clinical personnel of our customers has taken longer than expected. Our inability to supply green reloads for the i60 has resulted in lost revenue opportunities and together with the other factors described above, has slowed the rate of adoption of our i60 instrument. Further delays in the availability of green reload cartridges, or in other planned product releases, or our inability to quickly resolve perceived quality issues and other factors affecting the success of our i60 product launch, could have a material adverse effect on our revenues and results of operations. Customers may forego purchases of our existing products and purchase our competitors' products as a result of delays in the introduction of our new products and enhancements, failure by us to choose correctly among technical alternatives or failure by us to offer innovative products or enhancements at competitive prices and in a timely manner. In addition, announcements of new products by us or by competitors may result in a delay in or cancellation of purchasing decisions in anticipation of such new products. Any such losses could impair the value of your investment.

**We have limited manufacturing experience, have experienced significant manufacturing problems in the past, and may encounter difficulties in increasing production to provide an adequate supply to customers.**

The manufacture of our products is a complex and costly operation involving a number of separate processes and components. To date, our manufacturing activities have consisted primarily of assembling limited quantities of our products. We have considered, and will continue to consider as appropriate, manufacturing components that are currently provided by third parties, as well as implementing new production processes. We do not have experience in manufacturing our products in the commercial quantities that might be required to market our products in the United States, Europe and Japan. During 2006, we experienced significant difficulties in our supply chain and manufacturing operations, which impaired our ability to ship our products on a timely basis and had a material adverse impact on our results of operations for 2006. Similarly, throughout 2007 and the first quarter of 2008, we have experienced delays in the availability from a third party vendor of a critical component necessary to enable us to assemble one of the two sizes of reload cartridge that are used in our PLC 60 and i60 linear stapler. Our inability to ship reload cartridges in this size has adversely affected our ability to generate revenue from the PLC 60 devices we have placed in hospitals. We currently expect to resume shipping these reload cartridges in the second quarter of 2008. Manufacturing of our products in commercial quantities will require us to expand our manufacturing capabilities and to hire and train additional personnel. We expect that any expansion would be achieved through modified space utilization in our current leased facilities, improved efficiencies, increased automation and acquisition of

additional tooling and equipment. We may encounter difficulties in increasing our manufacturing capacity and in manufacturing commercial quantities, including:

- maintaining product yields;
- maintaining quality control and assurance;
- providing component and service availability;
- maintaining adequate control policies and procedures; and
- hiring and retaining qualified personnel.

Difficulties encountered in increasing our manufacturing capacity could impact our ability to adequately supply our customers.

**In order to achieve and sustain profitability, we must substantially improve our gross margins.**

The historical unit costs for our products, based on limited manufacturing volumes, have been very high in relation to our sales, resulting in low or negative gross margins. It will be necessary for us to achieve substantial further reductions in our cost of sales as a percentage of sales in order to become profitable. The transition to in-house production or to new production processes may initially have a negative effect on our manufacturing yields or costs, which would materially and adversely affect our business, financial condition and results of operations. Certain of our manufacturing processes are labor intensive, and achieving significant cost reductions will depend in part upon reducing the time required to perform these processes. We cannot assure you that we will be able to achieve the significant cost reductions in the manufacture of our products necessary for our business to achieve profitability.

**If our products are not considered to be a safe and effective alternative to existing technologies, we will not be commercially successful.**

Our Intelligent Surgical Instruments rely on new technology, and our success depends upon acceptance of this technology by the medical community as safe, clinically effective and cost effective and a preferred device as compared to products of our competitors. We have not collected, and are not aware that others have collected, long-term data regarding efficacy, safety and clinical outcomes associated with the use of our products. Any data that is generated in the future may not be positive or consistent with our current, largely anecdotal data, which would negatively affect market acceptance and the rate at which our Intelligent Surgical Instruments are adopted. Equally important will be physicians' perceptions of the safety of our products. Our technology is relatively new in surgery, and the results of short-term clinical experience with our SurgASSIST system do not necessarily predict long-term clinical benefits as compared to the products of our competitors. If, over the long term, our SurgASSIST system does not meet surgeons' expectations as to safety, efficacy and ease of use, the SurgASSIST system may not become widely adopted.

Even if the data collected from future clinical studies or clinical experience indicates positive results, each surgeon's actual experience with our device outside the clinical study setting may vary. Consequently, both short- and long-term results reported in any future clinical studies may be significantly more favorable than typical results of other practicing surgeons, which could negatively affect rates of adoption and negatively affect our results.

**Because our markets are highly competitive, customers may choose to purchase our competitors' products, which would result in reduced sales and harm our financial results.**

Our SurgASSIST system is a new technology and must compete with the more established manual devices of our competitors, such as Covidien and Ethicon Endo-Surgery, Inc. Conventional manual devices are widely accepted in the medical community, have a long history of use and do not require

the purchase of additional, expensive capital equipment. We cannot be certain that surgeons will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

Most of our competitors enjoy competitive advantages over us, including:

- significantly greater name recognition;
- longer operating histories;
- established relationships with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory clearance for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

In addition, our SurgASSIST system in its original configuration has certain perceived disadvantages compared to conventional manual endomechanical devices. Prior to the introduction of our new i60 linear stapler and our iDrive wireless handheld power and control system, our Intelligent Surgical Instruments had to be tethered by a flexible shaft to a power console which is located outside the sterile field. Some surgeons and operating room personnel found this to be cumbersome and not well suited for all procedures. This factor may initially have limited market acceptance of our SurgASSIST platform. Our next generation untethered self-contained Intelligent Surgical Instruments are designed to eliminate this disadvantage of our SurgASSIST system, but we may need to overcome an initial negative perception by clinicians of our first-generation tethered technology.

Our future success depends upon maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

- develop technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;
- obtain patent protection or other intellectual property rights that would prevent us from developing or enhancing our products; or
- obtain regulatory approval for the commercialization of their products more rapidly or effectively than we do.

Additional competitors also may enter our market. As a result, we cannot assure you that we will be able to compete successfully against existing or new competitors. Our sales would be reduced or eliminated if our competitors develop and market products that are more effective and less expensive than our products. Volatility in the demand for our products could, among other things, make it more difficult to gauge the manufacturing capacity necessary to meet our demand, decrease our manufacturing efficiency and increase our working capital requirements. If any of these occur, your investment in our common stock may decrease in value.

**We assemble our Intelligent Surgical Instruments using our own customized equipment and plan to undertake a new manufacturing process, making us vulnerable to production and supply problems that could negatively impact our sales.**

We presently use customized equipment for certain steps in the assembly of our Intelligent Surgical Instruments. Because of the customized nature of our equipment, we cannot rely on third parties to find new parts or replace the equipment. As a result, we are responsible for maintaining the equipment and for locating spare parts. If the equipment malfunctions and we are unable to locate spare parts or hire qualified personnel to repair the equipment, we may encounter delays in the manufacture of our Intelligent Surgical Instruments and reloads and may not have sufficient inventory to meet our customers' demands, which could adversely affect our business, financial condition and results of operations.

We have engaged a third party to develop and fabricate an automated system to enable us to assemble the reload cartridges for our PLC 60 and i60 linear staplers, which we currently assemble manually. We expect the system to be operational in the second quarter of 2008. While we believe the use of this new system should reduce our risk of supply problems, the automated system must be capable of manufacturing at our anticipated volume. However, there is no guarantee that the automated system will function at the capacity we require. The automated system will be located at our facility in Langhorne, Pennsylvania, which requires us to be responsible for the day-to-day control and protection of the system. Delay in the availability of, or unanticipated problems in our utilization of, this automated system could jeopardize our initiatives to improve our gross margins.

**We are dependent upon a number of key suppliers, including sole source suppliers, the loss of which would materially harm our business.**

We rely upon sole source suppliers for a number of key components and services used in manufacturing our products and, in general, we do not have long-term contracts with these suppliers. We cannot assure you that we will be able to obtain sufficient quantities of such components or services in the future. Because we do not have long-term contracts, our suppliers generally are not required to provide us with any guaranteed minimum production levels.

In addition, our reliance on third parties involves a number of risks, including, among other things:

- suppliers may fail to comply with regulatory requirements or make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipments of our products;
- we may not be able to respond to unanticipated changes and increases in customer orders;
- we may be subject to price fluctuations due to a lack of long-term supply arrangements for key components;
- we may experience delays in delivery by our suppliers due to changes in demand from us or their other customers;
- we may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems;
- fluctuations in demand for products that our suppliers manufacture for others may affect their ability or willingness to deliver components to us in a timely manner;
- our suppliers may wish to discontinue supplying components or services to us for risk management reasons;



- we may not be able to find new or alternative components or reconfigure our system and manufacturing processes in a timely manner if the necessary components become unavailable; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

If any of these risks materialize, it could significantly increase our costs and impact our ability to meet demand for our products.

We cannot quickly replace suppliers or establish additional new suppliers for some of these components, due to both the complex nature of the manufacturing process used by our suppliers and the time and effort that may be required to obtain regulatory clearance or approval to use materials from alternative suppliers. Any significant supply interruption or capacity constraints affecting our facilities or those of our suppliers would impair our ability to manufacture our products.

**If we are unable to manage our expected growth, our performance may suffer.**

As of March 28, 2008, we had approximately 177 employees, compared with 133 at December 31, 2006. We will need to continue to expand our managerial, operational, financial and other resources to manage and fund our operations, continue our research and development activities, increase the sales force and develop our products. It is possible that our management, finance, technical and regulatory personnel, systems and facilities currently in place may not be adequate to support the recent rapid growth in our operations, and our expected future growth. Our need to effectively manage our operations, growth and programs requires that we continue to improve our systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals. In March 2008, our chief operations officer, Alex Bourdon, resigned. Mr. Bourdon was one of our three executive officers and was responsible for our manufacturing operations as well as for our regulatory compliance operations. We have hired Michael M. Fard as vice president of operations, effective March 24, 2008. This transition in our senior management team may in the near term impair our ability to effectively manage our growing operations and to implement required systems improvements.

**We must upgrade and correct deficiencies in our regulatory compliance operations, and our failure to do so could impair our ability to market our products or lead to regulatory enforcement action against us.**

We are subject to extensive regulation in the United States and other countries, including by the United States Food and Drug Administration, or FDA. We maintain an organization of managers, engineers and administrative personnel, consisting of 22 persons at December 31, 2007, whose responsibility it is to ensure that our products, facilities and operations comply with applicable regulatory requirements. However, during 2007 we experienced shortages of qualified regulatory compliance staff due to turnover and illness, among other factors, and we need to upgrade and carefully manage our regulatory compliance operations in order to accommodate our expected growth. Additionally, the senior vice president of regulatory affairs and quality assurance whom we hired in the fourth quarter of 2007, resigned in January 2008. We currently are not seeking to recruit a successor for him, and have divided his responsibilities among several of our current employees. Our chief operations officer, Alex Bourdon, to whom our senior vice president of regulatory affairs and quality assurance reported, also resigned in March 2008.

In April 2007, following an inspection of our facilities, the FDA issued a Notice of Inspectional Observations, or Form 483, which included 24 inspectional observations, which are more fully described elsewhere in this report. We were also inspected by the FDA in 2002, 2003 and 2005, and some of the

observations in the FDA's April 2007 Form 483 are similar to those we received in earlier inspections. As a result of these events, we concluded that there are significant deficiencies in our regulatory compliance operations, and are taking steps to rectify these deficiencies. We also have begun the process of making needed improvements in our corrective and preventive action, complaint handling and medical device reporting procedures, in our processes for compliance with other requirements of the FDA's quality system regulations and in our related controls and internal audit functions. In late 2007 we engaged an independent consultant to audit our compliance with certain aspects of the FDA's quality system regulations. The consultant noted improvements in our complaint management, failure investigation, medical device report reporting, management review, internal audit and corrective and preventative action processes, but also identified areas for improvement in our FDA quality system regulations in each of these areas, some of which related to occurrences after the FDA's April 2007 Form 483.

If we are not successful in identifying and recruiting qualified personnel to manage and staff our regulatory compliance operations or in implementing necessary process improvements on a timely basis, we could be subject to regulatory enforcement actions which could damage our reputation, impair our ability to obtain regulatory clearances for new products, prevent us from manufacturing and selling our products and harm our business.

**We have a material weakness in our internal control over financial reporting, and if we are unable to achieve and maintain effective internal control over financial reporting, investors could lose confidence in our financial statements and our company, which could have a material adverse effect on our business and stock price.**

We have concluded that there is a material weakness in our internal control over financial reporting because we do not have a sufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve non-routine and complex accounting matters or to evaluate the impact of new and existing accounting pronouncements on our consolidated financial statements while completing the financial statement close process. The material weakness resulted in the identification of adjustments during the financial statement close process in 2007 that have been recorded in our consolidated financial statements. A material weakness is a control deficiency, or a combination of control deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements would not be prevented or detected. Until this design deficiency in our internal control over financial reporting is remediated, there is reasonable possibility that a material misstatement to our annual or interim consolidated financial statements could occur and not be prevented or detected by our internal controls in a timely manner.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, when we file our Annual Report on Form 10-K for the fiscal year ending December 31, 2008, we must assess the effectiveness of our internal control over financial reporting as of the end of our 2008 fiscal year. This assessment must include disclosure of any material weaknesses in our internal control over financial reporting that are identified by management. The report must also contain a statement that our independent registered public accounting firm has issued an attestation report on management's assessment of such internal controls.

If we are unable at that time to assert that our internal control over financial reporting is effective because the material weakness identified above has not been remediated, or for any other reason, or if our independent registered public accounting firm is unable to express an opinion on the effectiveness of our internal controls, investors could lose confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on our stock price.

**Any failure in our training efforts could result in lower than expected product sales and potential liabilities.**

A critical component of our sales and marketing efforts is the training of a sufficient number of surgeons, other clinicians and hospital staff to properly use our SurgASSIST system. In order to operate effectively, our internal sales force must also be trained on the benefits and proper utilization of our technology, including newly introduced products. In connection with the introduction of our i60 and iDrive products, we have found that it takes longer than we expected to adequately train our internal sales force and customers' clinical personnel on the use and care of these instruments, due in part to their novelty and to the need to employ new sterilization techniques. Additionally, the number of i60 and iDrive demonstration units available for use by our sales force was limited during the early phases of our i60 product launch. As a result, it has taken longer for our sales force to become fully effective in selling these new products, and the rate of adoption of our new technology has been adversely affected. Any further delays in adequately training our internal sales force or our customers' clinical personnel on these or other products could harm our business.

Additionally, we rely on clinicians and hospital staff to devote adequate time to learn to use our products. If surgeons or hospital staff are not properly trained in the use of our Intelligent Surgical Instruments, they may misuse or ineffectively use our products. For example, during 2007, we received reports of incomplete firings of our reusable PLC 60 instrument that we believed were attributable to improper installation of reload cartridges by our customers' medical personnel. More recently, we have received similar reports relating to the seating of reload cartridges in our i60 and PLC 75 linear staplers. We initiated improvements in our training procedures to alert customers to the need to properly seat the reload cartridges, and designed a new version of the reload cartridge to incorporate a positive locking feature to make this error less likely to occur. However, insufficient training may result in unsatisfactory patient outcomes, patient injury and related liability or negative publicity, which could have an adverse effect on our product sales.

**The use of our products could result in product liability claims that could be expensive, divert management's attention and harm our reputation and business.**

Our business exposes us to significant risks of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. The medical device industry has historically been subject to extensive product liability litigation. We have in the past been, and in the future may be, subject to claims by consumers, healthcare providers, third-party payors or others selling our products if the use of our products were to cause, or merely appear to cause, injury or death. We are currently the subject of a product liability suit in Belgium. Any weakness in training and service associated with our products may also result in product liability lawsuits. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or adequate amounts. A product liability claim, regardless of its merit or eventual outcome or the availability of insurance coverage, could result in:

- decreased demand for our products;
- injury to our reputation;
- diversion of management's attention;
- significant costs of related litigation;
- substantial monetary awards to patients;
- product recalls or market withdrawals;
- loss of sales; and
- the inability to successfully commercialize our products that are under development.

**If we deliver products with defects, our credibility may be harmed and market acceptance of our products may decrease.**

The manufacturing and marketing of our products involve an inherent risk of product liability claims. In addition, our product development and production processes are complex and could expose our products to defects. Additionally, problems experienced by our customers, such as difficulty in consistently seating our reload cartridges may be perceived by them as quality defects. Our SurgASSIST system also incorporates sophisticated computer software. Complex software frequently contains errors, especially when first introduced. We cannot assure you that our software will not experience errors or performance problems in the future. If our products have, or are perceived to have, mechanical defects or software errors or have performance problems, we would likely experience:

- loss of sales;
- delay in market acceptance of our products;
- damage to our reputation;
- additional regulatory filings;
- product recalls;
- increased service or warranty costs; or
- product liability claims.

**We may need substantial additional funding and we may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.**

We believe that the net proceeds from our recent initial public offering, together with our future sales, existing cash and cash equivalent balances and interest we earn on these balances, will be sufficient to meet our anticipated cash requirements through January 1, 2009. We have made no arrangements to obtain additional financing, and there can be no assurance that such financing, if required or desired, will be available in amounts or on terms acceptable to us, if at all. These conditions raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has modified its audit report on our consolidated financial statements to include an explanatory paragraph regarding this contingency. However, our actual capital requirements will depend on many factors, many of which are outside our control, including:

- future revenue generation;
- the cost of filing and prosecuting patent applications and defending and enforcing our patent and other intellectual property rights;
- the cost of defending, in litigation or otherwise, any claims that we infringe third party patent or other intellectual property rights;
- the cost and timing of regulatory approvals;
- expenses of future clinical studies, if any;
- the effect of competing technological and market developments;
- licensing technologies for future development; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

Historically, we have financed our operations and internal growth primarily through private placements of equity securities and debt and, more recently, our initial public offering. We cannot be certain that additional public or private financing will be available in amounts acceptable to us, or at all. If we raise additional funds by issuing equity securities, dilution may occur. Debt financing, if available, may involve restrictive covenants. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. Substantially all our assets are subject to a security interest in favor of the holders of our convertible notes, which may limit our ability to obtain additional debt financing. Additionally, if we default in the payment of our convertible notes, our noteholders will be entitled to exercise their rights as secured creditors, which include the right to foreclose on the assets we have provided as collateral, which could materially impair our ability to continue to operate our business.

If we are unable to raise additional funds when needed, we may have to delay or reduce the scope of or eliminate some or all of our development programs or we may be forced to seek protection under applicable bankruptcy laws. Any restructuring or bankruptcy could materially impair your investment.

**We sell our systems internationally and are subject to various risks relating to these international activities, which could adversely affect our business, financial condition and results of operations.**

In 2007, 18% of our sales occurred in international markets. In 2006, 21% of our sales occurred in international markets. By doing business in international markets, we are exposed to risks separate and distinct from those we face in our domestic operations. Our international business may be adversely affected by changing economic conditions in foreign countries. Because most of our international sales are denominated in the functional currency of the country where the product is being shipped, increases or decreases in the value of the U.S. dollar relative to foreign currencies could affect our results of operations. Engaging in international business inherently involves a number of other difficulties and risks, including:

- export restrictions and controls relating to technology and government regulation;
- the availability and level of reimbursement within prevailing foreign healthcare payment systems;
- pricing pressure that we may experience internationally;
- required compliance with existing and changing foreign regulatory requirements and laws;
- laws and business practices favoring local companies;
- longer payment cycles;
- difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs and other trade barriers;
- international terrorism and anti-American sentiment;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties in enforcing intellectual property rights.

Our exposure to each of these risks may increase our costs, impair our ability to market and sell our products and require significant management attention. We cannot assure you that one or more of these factors will not harm our business.

**If we choose to acquire or invest in new and complementary businesses, products or technologies instead of developing them ourselves, such acquisitions or investments could disrupt our business.**

We may attempt to expand our business through acquisitions. To the extent we grow our business through acquisitions, our future success may be partially dependent upon our ability to effectively integrate acquired businesses with our own. There can be no assurance that our acquisitions will be successfully integrated or that any such acquisitions will otherwise be successful. If our acquisitions are unsuccessful for any reason, our business may be harmed and the value of your investment may decline.

**We are dependent upon key personnel, the loss of any of which could harm our business.**

Our future business and operating results depend significantly on the continued contributions of our key technical personnel and senior management, particularly those of our co-founder, Chief Executive Officer and President, Michael P. Whitman. These individuals and the services they provide would be difficult or impossible to replace. While we are subject to certain severance obligations to Mr. Whitman, either he or we may terminate his employment at any time and for any lawful reason or for no reason. Our business and future operating results also depend significantly on our ability to attract and retain qualified management, manufacturing, technical, regulatory, marketing, sales and support personnel for our operations. Competition for such personnel is intense, and there can be no assurance that we will be successful in attracting or retaining such personnel.

Although we have key-person life insurance in the amount of \$2.0 million on the life of Mr. Whitman, this amount would not fully compensate us for the loss of Mr. Whitman's services. The loss of key employees, the failure of any key employee to perform or our inability to attract and retain skilled employees, as needed, could harm our business.

**Lack of third-party coverage and reimbursement for our products could delay or limit their adoption.**

We may experience limited sales growth resulting from limitations on reimbursements made to purchasers of our products by third-party payors, and we cannot assure you that our sales will not be impeded and our business harmed if third-party payors fail to provide reimbursement that hospitals view as adequate.

In the United States, our products are purchased primarily by medical institutions, which then bill various third-party payors, such as the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, and other government programs and private insurance plans, for the healthcare services provided to their patients. The process involved in applying for coverage and incremental reimbursement from CMS is lengthy and expensive.

Moreover, many private payors look to CMS in setting their reimbursement policies and amounts. If CMS or other agencies limit coverage for procedures utilizing our SurgASSIST system or decrease or limit reimbursement payments for doctors and hospitals, this may affect coverage and reimbursement determinations by many private payors.

If a medical device does not receive incremental reimbursement from CMS, then a medical institution would have to absorb the cost of our products as part of the cost of the procedure in which the products are used. Acute care hospitals are now generally reimbursed by CMS for inpatient operating costs under a Medicare hospital inpatient prospective payment system. Under the Medicare hospital inpatient prospective payment system, acute care hospitals receive a fixed payment amount for each covered hospitalized patient based upon the Diagnosis-Related Group, or DRG, to which the inpatient stay is assigned, regardless of the actual cost of the services provided. At this time, we do not know the extent to which medical institutions would consider insurers' payment levels adequate to cover the cost of our products. Failure by hospitals and surgeons to receive an amount that they consider to be adequate reimbursement for procedures in which our products are used could deter

them from purchasing our products and limit our sales growth. In addition, pre-determined DRG payments may decline over time, which could deter medical institutions from purchasing our products. If medical institutions are unable to justify the costs of our products, they may refuse to purchase them, which would significantly harm our business.

**Our operations are currently conducted primarily at a single location that may be at risk from fire, earthquakes, terror attacks or other disasters.**

We currently conduct all of our manufacturing and management activities and certain research and development activities at a single location in Langhorne, Pennsylvania. We have taken precautions to safeguard our facilities, including insurance, health and safety protocols and off-site storage of computer data. However, a casualty due to fire or natural disaster, such as an earthquake, storm or terrorist attack, could cause substantial delays in our operations, damage or destroy our equipment or inventory and cause us to incur additional expenses. A disaster could seriously harm our business and results of operations. Our insurance does not cover earthquakes and floods and may not be adequate to cover our losses in any particular case.

### **Risks Related to Our Intellectual Property**

**If we fail to adequately enforce or defend our intellectual property rights, our business may be harmed.**

Much of the technology used in the markets in which we compete is covered by patents, and our commercial success will depend in large part on our ability to obtain and maintain patent and trade secret protection for our products and methods. We currently hold 24 issued United States patents, five granted European patents, more than 100 pending United States and foreign patent applications and two licensed patents that cover key aspects of our technology. Our issued patents expire at various dates beginning in 2019. The loss of our patents could reduce the value of the related products. In addition, the cost to litigate infringements of our patents or the cost to defend ourselves against patent infringement actions by others could be substantial.

Our ability to obtain additional patents is uncertain and the legal protection afforded by these patents is limited and may not adequately protect our rights or permit us to gain or keep any competitive advantage. In addition, the specific content required of patents and patent applications that is necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or in interpretations of patent laws in the United States or elsewhere may diminish the value of our intellectual property or narrow the scope of our patent protection. Even if patents are issued regarding our products and methods, our competitors may challenge the validity of those patents. Patents also will not protect our products and methods if competitors devise ways of making competitive products without infringing our patents.

Proprietary trade secrets and unpatented know-how are also very important to our business. We rely on trade secrets to protect certain aspects of our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Our employees, consultants, contractors, outside clinical collaborators and other advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

**If we infringe intellectual property rights of third parties, it may increase our costs or prevent us from being able to sell our existing products or commercialize new products.**

There is a risk that we are infringing the proprietary rights of third parties under patents and pending applications belonging to third parties that may exist in the United States and elsewhere in the world and that relate to the products we market and develop. Because the patent application process can take several years to complete, there may be currently pending applications, unknown to us, which may result in issued patents that cover the production, manufacture, commercialization or use of our products. In addition, the production, manufacture, commercialization or use of our product candidates may infringe existing patents of which we are not aware.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the medical device industry. Defending ourselves against third-party claims, including litigation in particular, would be costly and time consuming and would divert management's attention from our business, which could lead to delays in our development or commercialization efforts. Currently, we are involved in two appeal proceedings in Germany in connection with two of three patent-infringement lawsuits against us. The lawsuits alleged that certain of our products infringe three European patents held by Ethicon Endo-Surgery. We prevailed in two of the three infringement actions and the products in question were found not to infringe the Ethicon Endo-Surgery patents, and Ethicon Endo-Surgery is appealing one of those decisions. We lost the other infringement action and are appealing that decision. If third parties are successful in their claims, we might have to pay substantial damages or take other actions that are adverse to our business. As a result of intellectual property infringement claims, or to avoid potential claims, we might:

- be prohibited from selling or licensing any of our current products or any product that we may develop unless the patent holder licenses the patent to us, which it is not required to do;
- be required to pay substantial royalties or grant a cross license to our patents to another patent holder; or
- be required to redesign a product so it does not infringe, which may not be possible or could require substantial funds and time.

**We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.**

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. In addition, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and be a distraction to management.



## **Risks Related to Regulatory Compliance**

**Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities.**

Our facilities and manufacturing techniques generally must conform to standards that are established by the United States Food and Drug Administration, or FDA, and other government agencies, including those of European and other foreign governments. These regulatory agencies may conduct periodic audits or inspections of our facilities or our processes to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we have failed to comply with the appropriate regulatory standards, it may impose fines on us, delay or withdraw pre-market clearances or other regulatory approvals or, if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Between May 2002 and June 2005, the FDA conducted three inspections of our facilities. Each of those inspections resulted in the issuance of a Notice of Inspectional Observations, or Form 483. Certain observations regarding our processes to handle customer complaints, submit medical device reports, initiate corrective and preventive actions and to conduct internal quality audits were identified by the FDA as areas of possible non-compliance with FDA regulations. For each of those Form 483s issued by the FDA, we submitted a response which identified our proposed corrective action plans to address the FDA's inspectional observations. In each case, the FDA issued an Establishment Inspection Report, or EIR, which officially closed FDA's inspection. From February 13 to April 26, 2007, the FDA conducted an additional inspection of our facility in Langhorne, Pennsylvania. A Form 483 was provided to us at the conclusion of the inspection. In the FDA's most recent Form 483, 24 inspectional observations were identified, including the failure to properly process customer complaints, failure to submit to the FDA medical device reports or to submit them within regulatory timeframes, and the lack of reporting a field action. Certain of the FDA's inspectional observations are similar to observations identified in the prior Form 483s issued to us. We prepared and submitted a response to the FDA, which included our proposed corrective actions to address the FDA's observations. Whether the FDA will accept our response is uncertain, particularly in light of the similar nature of the current inspectional observations to the previous observations. If the FDA does not agree with our proposed corrective actions, or accepts them but finds that we have not implemented them adequately, if the FDA is concerned about the repetitive nature of the inspectional observations, or if we otherwise fail to comply with applicable regulatory requirements, the FDA could initiate an enforcement action, including any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval, or PMA, of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

**We may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.**

The federal anti-kickback laws and several similar state laws prohibit payments that are intended to induce physicians or others either to refer patients to acquire or arrange for or recommend the acquisition of healthcare products or services. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements and sales programs we may have with hospitals, physicians or other potential purchasers or users of medical devices. In particular, these laws influence how we structure our sales, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with applicable requirements, these laws are broadly written and it is difficult to determine precisely how these laws will be applied in specific circumstances. We could be subject to a claim under these anti-kickback laws for our consulting arrangements with surgeons, grants for training and other education, grants for research and other interactions with doctors which have come under scrutiny by federal and state regulators and law enforcement entities. Anti-kickback laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial. Due to the breadth of the statutory provisions and the lack of guidance in the form of regulations or court decisions addressing some industry activities, it is possible that our sales, marketing and promotional activities practices might be challenged under anti-kickback or related laws. Even an unsuccessful challenge to or investigation into our practices could cause adverse publicity and thus could harm our business and results of operations.

Foreign sales of our products also subject us to similar fraud and abuse laws, including application of the U.S. Foreign Corrupt Practices Act. If our operations, including any consulting arrangements we may enter into with physicians who use our products, are found to be in violation of these laws, we or our officers may be subject to civil or criminal penalties, including large monetary penalties, damages, fines, imprisonment and exclusion from Medicare and Medicaid program participation. If enforcement action were to occur, our business and financial condition would be harmed.

**Modifications to our products may require new regulatory clearances or approvals or may require us to recall or cease marketing our products until clearances or approvals are obtained.**

Modifications to our products may require new regulatory approvals or clearances, including 510(k) clearances or premarket approvals, or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. The FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine that a modification could not significantly affect safety or efficacy and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. However, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. We have made modifications to our products in the past and may make additional modifications in the future that we believe do not or will not require additional clearances or approvals. If the FDA disagrees and requires new clearances or approvals for the modifications, we may be required to recall and to stop marketing our products as modified, which could require us to redesign our products and harm our operating results. In these circumstances, we may be subject to significant enforcement actions.

If a manufacturer determines that a modification to an FDA-cleared device could significantly affect its safety or efficacy, or would constitute a major change in its intended use, then the manufacturer must file for a new 510(k) clearance or possibly a premarket approval application. Where we determine that modifications to our products require a new 510(k) clearance or premarket approval application, we may not be able to obtain those additional clearances or approvals for the modifications or additional indications in a timely manner, or at all. For those products sold in the European Union,

we must notify Orion Registrar, Inc., or Orion, our E.U. Notified Body, if significant changes are made to the products or if there are substantial changes to our quality assurance systems affecting those products. Obtaining clearances and approvals can be a time consuming process, and failure to obtain or delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

**There is no guarantee that the FDA will grant 510(k) clearance or PMA approval of our emerging technologies and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.**

Some of our new products, such as our proposed i60RB4 and i45V linear staplers, will require FDA clearance of a 510(k), or may even require FDA approval of a PMA. We are in the process of developing our regulatory strategies for obtaining clearance or approval of these new products. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for 510(k) clearance or premarket approval of new products, new intended uses or modifications to existing products. Failure to receive clearance or approval for our new products would have an adverse effect on our ability to expand our business.

**If we or our contract manufacturers fail to comply with the FDA's Quality System Regulations, our manufacturing operations could be interrupted and our product sales and operating results could suffer.**

Our finished goods manufacturing processes, and those of some of our contract manufacturers, are required to comply with the FDA's Quality System Regulations, or QSRs, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA enforces its QSRs through periodic inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. If our manufacturing facilities or those of any of our contract manufacturers fail to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action, including any of the following sanctions, which could have a material impact on our operations:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances on PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

**Our products may in the future be subject to product recalls that could harm our reputation, business and financial results.**

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture. In the case of the FDA, the authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. In addition, foreign

governmental bodies have the authority to require the recall of our products in the event of material deficiencies or defects in design or manufacture. Manufacturers may, under their own initiative, recall a product if any material deficiency in a device is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We have initiated certain voluntary recalls involving products that have been distributed to our customers and may take additional such actions in the future. We believe that certain of those recalls do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action, including any of the following sanctions for failing to report the recalls when they were conducted:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement, refunds, recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

**If our products, or malfunction of our products, cause or contribute to a death or a serious injury, we will be subject to medical device reporting regulations, which can result in voluntary corrective actions or agency enforcement actions.**

Under the FDA medical device reporting regulations, medical device manufacturers are required to report to the FDA information that a device has or may have caused or contributed to a death or serious injury or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or one of our similar devices were to recur. All manufacturers placing medical devices in the market in the European Union are legally bound to report any serious or potentially serious incidents involving devices they produce or sell to the Competent Authority in whose jurisdiction the incident occurred. Were this to happen to us, the relevant Competent Authority would file an initial report, and there would then be a further inspection or assessment if there are particular issues. This would be carried out either by the Competent Authority or it could require that Orion, as the Notified Body, carry out the inspection or assessment.

Any such adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events involving our products have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results. Failure to report such adverse events to appropriate government authorities on a timely basis, or at all, could result in an enforcement action against us.

**Failure to obtain regulatory approval in additional foreign jurisdictions will prevent us from expanding the commercialization of our products abroad.**

We intend to market our products in a number of international markets. Although certain of our products have been approved for commercialization in Japan and in the European Union, in order to market our products in other foreign jurisdictions we must obtain separate regulatory approvals. The approval procedure varies among jurisdictions and can involve substantial additional testing. Approval or clearance by the FDA does not ensure approval by regulatory authorities in other jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign jurisdictions or by the FDA. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. In addition, the time required to obtain foreign approval may differ from that required to obtain FDA approval, and we may not obtain foreign regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any foreign market other than in the European Union and Japan.

**We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses.**

Our promotional materials and training methods for surgeons must comply with FDA and other applicable laws and regulations. Many of our products are cleared by the FDA for use in various surgical applications. We believe that the specific surgical procedures for which our products are marketed fall within the scope of the surgical applications that have been cleared by the FDA. However, the FDA could disagree and require us to stop promoting our products for those specific procedures until we obtain FDA clearance or approval for them. In addition, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement. In that event, our reputation could be damaged and adoption of the products would be impaired.

**Federal regulatory reforms may adversely affect our ability to sell our products profitably.**

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted or FDA regulations, guidance or interpretations changed, and what the impact of such changes, if any, may be.

Without limiting the generality of the foregoing, Congress has recently enacted, and the President has signed into law, the Food and Drug Administration Amendments Act of 2007. The amendments require, among other things, that FDA propose, and ultimately implement, regulations that will require manufacturers to label medical devices with unique identifiers unless a waiver is received from FDA. Once implemented, compliance with those regulations may require us to take additional steps in the manufacture of our products and labeling. These steps may require additional resources and could be costly. In addition, the law, as amended, will require us to, among other things, pay annual establishment registration fees to the FDA for each of our FDA registered facilities.

## **Risks Related to Ownership of Our Common Stock**

**We expect that the price of our common stock will fluctuate substantially.**

Until our recent initial public offering, there was no public market for shares of our common stock. Since our initial public offering in October 2007, the market price of our common stock has ranged from \$5.80 to \$14.64. The market price for our common stock is likely to continue to fluctuate as a result of a number of factors, including:

- actual or anticipated announcements of technological innovations;
- introduction by us or by others of new commercial products;
- actual or anticipated changes in laws and governmental regulations;
- disputes relating to patents or proprietary rights;
- changes in business practices;
- developments relating to our efforts to obtain additional financing to fund our operations or our issuance of additional debt or equity securities;
- announcements by us regarding transactions with potential strategic partners;
- changes in industry trends or conditions;
- trading volume of our common stock;
- changes in earnings estimates or recommendations by securities analysts, failure to obtain analyst coverage of our common stock or our failure to achieve analysts' earnings estimates;
- developments in our industry; and
- general market conditions and other factors unrelated to our operating performance or the operating performance of our competitors or potential competitors.

Stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. In the past, securities class action litigation often has been initiated against a company following a period of volatility in the market price of the company's securities. If securities class action litigation is initiated against us, we will incur substantial costs and our management's attention will be diverted from our operations. All of these factors may materially and adversely affect the market price of our common stock, and you may lose some or all of your investment.

**Securities analysts may not initiate or continue coverage for our common stock or may issue negative reports, and this may have a negative impact on the market price of our common stock.**

Securities analysts may elect not to provide research coverage of our common stock, and if a sufficient number of securities analysts do not cover our common stock, the lack of research coverage may adversely affect the market price of our common stock. The trading market for our common stock may be affected in part by the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts who elect to cover us downgrades our stock, our stock price could decline. If one or more of these analysts ceases coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. In addition, rules mandated by the Sarbanes-Oxley Act and a global settlement reached in 2003 between the Securities and Exchange Commission, or SEC, other regulatory agencies and a number of investment banks have led to a number of fundamental changes in how analysts are reviewed and compensated. In particular, many investment banking firms will be required to contract with independent financial analysts for their stock research. It may be difficult for companies such as ours, with smaller market capitalizations, to

attract independent financial analysts that will cover our common stock. This could have a negative effect on the market price of our stock.

**Our principal stockholders, directors and management own a large percentage of our voting stock, which allows them to exercise significant influence over matters subject to stockholder approval.**

Our executive officers, directors and stockholders holding 5% or more of our outstanding common stock beneficially own or control approximately 40.8% of the outstanding shares of our common stock, assuming no exercise of outstanding options and warrants or conversion of our convertible notes. Accordingly, these executive officers, directors and principal stockholders, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control or otherwise discourage a potential acquirer from attempting to obtain control of our company, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

**Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control of our company.**

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, may discourage, delay or prevent a merger, acquisition or change of control. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors and take other corporate actions. These provisions include:

- advance notice requirements for stockholder proposals and nominations;
- limitations on convening stockholder meetings;
- the elimination of stockholder action by written consent;
- the elimination of cumulative voting; and
- a classified board of directors.

In addition, we are subject to Section 203 of the Delaware General Corporation Law, which imposes certain restrictions on mergers and other business combinations between us and any holder of 15% or more of our common stock.

**Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.**

If our existing stockholders sell substantial amounts of our common stock in the public market, or the public market perceives that existing stockholders might sell substantial shares of common stock, the market price of our common stock could decline significantly. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

Approximately 2.7 million shares of our common stock that are issuable upon conversion of the convertible notes that we issued in March 2007 are now eligible for resale under Rule 144. Approximately 17.1 million additional shares of our common stock are outstanding, assuming no exercise of outstanding options or warrants or conversion of our convertible notes. Of these, 12.5 million shares are held by existing stockholders who are subject to lock-up agreements with the underwriters of our initial public offering which prohibit the sale of such shares until at least April 22, 2008. If the holders of these restricted shares sell them or are perceived by the market as intending to sell them when these restrictions on resale end, the market price of our common stock could drop significantly. Any substantial sale of common stock pursuant to any resale registration statements or Rule 144 may have an adverse effect on the market price of our common stock by creating an excessive supply.

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

We currently lease approximately 44,000 square feet in Langhorne, Pennsylvania, which is used as our headquarters and principal manufacturing facility. The Langhorne facility contains approximately 35,000 square feet of manufacturing space, 1,000 square feet of research and development space and 4,000 square feet devoted to administrative offices. This facility is leased through March 31, 2012.

In September 2006, we moved the majority of our research and development activities to Shelton, Connecticut where we currently lease approximately 5,456 square feet. This facility is leased through September 19, 2011. In December 2006 we opened a sales office in Japan concurrently with the creation of our Japanese subsidiary, PMI Japan. We conduct our European administrative, sales and distribution operations through our German and French subsidiaries, Power Medical Interventions Deutschland GmbH and Power Medical Interventions France SA. Power Medical Interventions Deutschland GmbH leases office space in Hamburg, Germany and Power Medical Interventions France SA leases office space in Toulouse, France.

In January 2008 we entered into a twelve month lease for 2,125 square feet of office space in New Hope, Pennsylvania which is used for administrative offices for our senior executive team. We have an option to extend the term of this lease for an additional twelve months.

We believe that our existing facilities should meet our needs for at least the next 24 months.

**Item 3. Legal Proceedings.**

*Product liability suit in Belgium.* In early December 2004, we were made a party to a lawsuit filed in a Belgian court on September 30, 2004 by a patient and his co-habiting female partner against the insurer for a Belgian surgeon and hospital as well as against PMI's former Belgian distributor. The complaint alleged that the patient suffered injuries as a result of a surgery performed using one of our surgical instruments. The complaint alleged that our instrument was "deficient" and claimed estimated damages in the amount of €100,000 with "reservation for modification during the proceedings." We have notified our insurance carrier of the lawsuit, and the carrier has not disclaimed coverage. We intend to continue to contest the claim with the assistance of U.S. and Belgian counsel.

*Patent litigation against Ethicon Endo-Surgery in Germany.* In March 2005, Ethicon Endo-Surgery initiated three patent infringement lawsuits against us and our German subsidiary in district court in Düsseldorf, Germany. The lawsuits allege that certain of our products infringe the German parts of three European patents owned by Ethicon Endo-Surgery, which we refer to as the Hooven, Clark and Rothfuss patents. We hired German counsel to defend the patent infringement cases and to seek revocation of Ethicon Endo-Surgery's patents in nullity proceedings before a separate court in Munich, Germany.

We prevailed in the Hooven patent infringement action, and the products in question were found not to infringe this patent. Ethicon Endo-Surgery did not appeal the infringement decision, and the case is closed. In the related nullity action, the Hooven patent was upheld in a modified form. No appeal was taken and the case is now closed.

We prevailed in both the infringement and nullity actions related to the Clark patent; the products in question were found not to infringe this patent, and the nullity court declared the asserted patent revoked. Ethicon Endo-Surgery is appealing both the infringement and nullity decisions. The infringement appeal has been stayed by the appellate court until the final outcome of the nullity proceedings, which is not expected before 2010.



We lost the infringement action related to the Rothfuss patent, which concerns a particular stapling cartridge that can be used in our surgical instruments. We are appealing that infringement decision. We prevailed in the nullity action related to the Rothfuss patent, and the nullity court declared the asserted patent revoked. Ethicon has appealed this decision.

In the Rothfuss infringement action, Ethicon Endo Surgery asserts that it is entitled to collect damages of approximately €526,000, and has instituted damages proceedings for part of its claim, asking the Düsseldorf court for a partial damages award of at least €142,000, or alternatively, €263,000.

We introduced a redesigned stapling product that would not infringe the Rothfuss patent even if the patent and the infringement decision were upheld. Subsequently, the appeal court stayed the provisional enforcement of the district court ruling in Ethicon Endo-Surgery's favor in the Rothfuss patent infringement litigation and we re-introduced the product accused of infringement in that case.

Ethicon Endo-Surgery is appealing the Rothfuss patent nullity decision. The courts before which the Rothfuss infringement appeal and the damages action are pending stayed those proceedings until final resolution of the Rothfuss nullity action, which is not expected before 2010.

In the event Ethicon Endo-Surgery were to prevail in its appeals of the Clark patent decisions or in its appeal of the Rothfuss nullity action decision, we may be precluded from selling certain of our products in Germany.

**Item 4. *Matters Submitted to a Vote of Security Holders.***

No matters were submitted to a vote of our security holders during the fourth quarter of the fiscal year ended December 31, 2007.

## PART II

### Item 5. *Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.*

The following table sets forth, for the periods indicated, the range of high and low sale prices for our common stock. Our common stock trades on the Nasdaq Global Market under the symbol PMII. Trading of our common stock commenced on October 26, 2007, as a result of our initial public offering.

	<u>High</u>	<u>Low</u>
<b>Year ended December 31, 2007</b>		
Fourth quarter (commencing October 26, 2007) .....	\$14.79	\$10.90

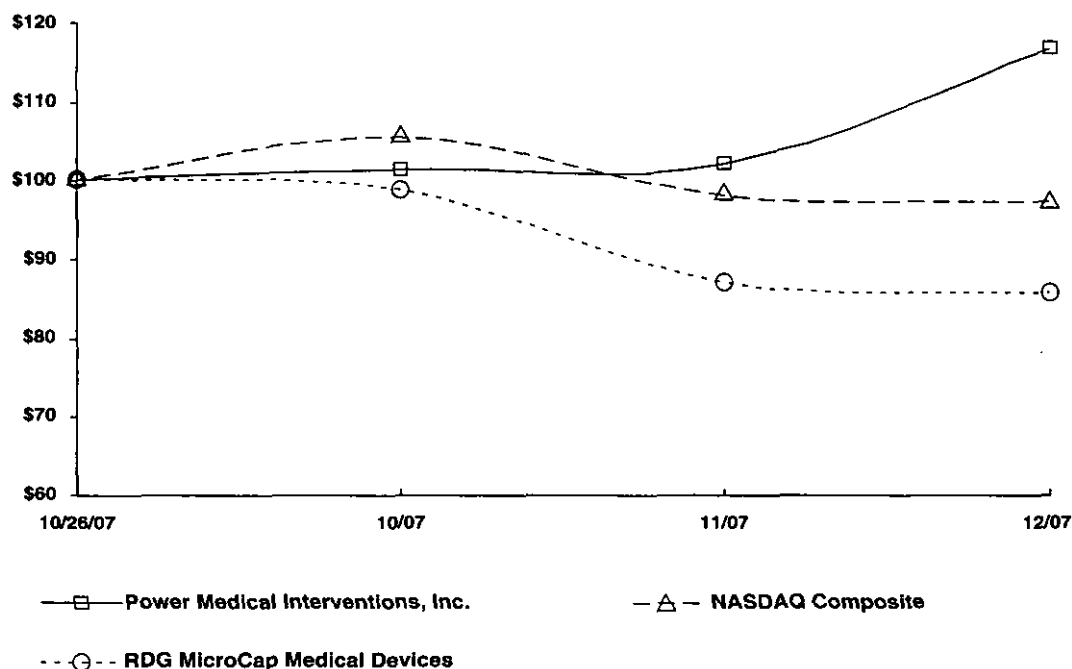
Through March 28, 2008, we have used approximately \$18.5 million of the \$42.0 million of net proceeds of our initial public offering in October 2007 to fund our operations and for working capital purposes. We intend to use the balance of the proceeds for general corporate purposes, including working capital, the expansion of our sales and marketing organizations, continuation of our research and development efforts, expansion of our manufacturing capabilities and purchases of capital equipment. We may also use a portion of the proceeds for acquisitions of businesses, products and technologies that are complementary to our business.

As of December 31, 2007, our common stock was held by approximately 575 shareholders of record.

We did not repurchase any shares of our common stock in the fourth quarter of fiscal 2007.

#### COMPARISON OF 2 MONTH CUMULATIVE TOTAL RETURN\*

Among Power Medical Interventions, Inc., The NASDAQ Composite Index  
And The RDG MicroCap Medical Devices Index



\*\$100 invested on 10/26/07 in stock or 9/30/07 in index-including reinvestment of dividends. Fiscal year ending December 31.

# **Item 6. Selected Consolidated Financial Data.**

The selected consolidated financial data set forth below are derived from our consolidated financial statements. The consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 are derived from our audited consolidated financial statements included elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2004 and 2003 and the consolidated balance sheet data at December 31, 2005, 2004 and 2003 are derived from our audited consolidated financial statements which are not included in this report. The selected consolidated financial data should be read in conjunction with our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this report. Our historical results are not necessarily indicative of results to be expected for any future period.

	Year Ended December 31,				
	2007	2006	2005	2004	2003
	(in thousands, except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Sales .....	\$ 7,812	\$ 7,881	\$ 11,999	\$ 8,663	\$ 7,195
Cost of sales .....	6,676	10,066	12,346	7,244	9,121
Gross profit .....	1,136	(2,185)	(347)	1,419	(1,926)
<b>Costs and expenses:</b>					
Research and development .....	6,209	4,682	5,482	3,246	2,381
Sales and marketing .....	19,703	13,367	14,630	11,631	7,149
General and administrative .....	9,959	7,371	6,331	4,541	4,191
Operating loss .....	(34,735)	(27,605)	(26,790)	(17,999)	(15,647)
<b>Other income (expense):</b>					
Interest income .....	866	544	270	139	12
Interest expense .....	(2,976)	(1,269)	(916)	(564)	(593)
<b>Total other income (expense) .....</b>	<b>(2,110)</b>	<b>(725)</b>	<b>(646)</b>	<b>(425)</b>	<b>(581)</b>
Net loss .....	\$(36,845)	\$(28,330)	\$(27,436)	\$(18,424)	\$(16,228)
Accretion of preferred stock .....	(7,550)	(7,108)	(4,808)	(1,966)	(119)
Net loss applicable to common shares .....	<u>\$(44,395)</u>	<u>\$(35,438)</u>	<u>\$(32,244)</u>	<u>\$(20,390)</u>	<u>\$(16,347)</u>
<b>Net loss per common share:</b>					
Basic and diluted .....	<u>\$ (7.34)</u>	<u>\$ (9.44)</u>	<u>\$ (8.90)</u>	<u>\$ (6.13)</u>	<u>\$ (11.20)</u>
<b>Weighted average number of common shares outstanding:</b>					
Basic and diluted .....	<u>6,048</u>	<u>3,756</u>	<u>3,621</u>	<u>3,327</u>	<u>1,459</u>

	As of December 31,				
	2007	2006	2005	2004	2003
	(in thousands)				
<b>Consolidated Balance Sheet Data:</b>					
Cash and cash equivalents . . . . .	\$36,592	\$ 8,684	\$ 7,933	\$ 21,632	\$ 777
Working capital . . . . .	39,409	10,535	7,398	21,526	176
Total assets . . . . .	57,973	22,142	23,869	31,531	6,654
Long-term debt, net of current portion . . . . .	24,743	377	6,769	10,010	15,000
Redeemable convertible preferred stock . . . . .	—	116,198	73,331	51,988	6,181
Shareholders' equity (deficit) . . . . .	23,540	(100,029)	(66,538)	(37,409)	(20,239)

## **Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion in conjunction with our consolidated financial statements and notes thereto appearing elsewhere in this report. In addition to historical consolidated financial information, the following discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results could differ materially from those anticipated by these forward-looking statements as a result of many factors, including those discussed under "Risk Factors" and elsewhere in this report.*

### **Overview**

We design, manufacture and market the SurgASSIST® system of computer-assisted, power-actuated endomechanical surgical instruments, which we refer to as Intelligent Surgical Instruments™. Surgeons use our Intelligent Surgical Instruments for cutting, stapling and tissue manipulation in a variety of procedures in open surgery, minimally invasive surgery, or MIS, and in the emerging field of natural orifice transluminal endoscopic surgery, or NOTES. Our SurgASSIST system has been used in at least 30,000 surgical procedures in more than 350 hospitals and medical institutions worldwide.

Since our inception, we have devoted substantially all our resources to the development and commercialization of our SurgASSIST system and, more recently, to the expansion of our manufacturing and direct sales and marketing operations. We currently outsource the manufacture of components such as machined and molded parts, mechanical sub-assemblies and circuit boards and perform the final assembly and testing of our products in our Langhorne, Pennsylvania facility. We sell our Intelligent Surgical Instruments through our direct sales force in the United States, parts of Europe and Japan and through distributors in other parts of Europe.

We have incurred net losses in each year since our inception and have an accumulated deficit at December 31, 2007 of \$173.9 million. We expect our losses to continue through at least 2008 as we develop and introduce our next generation of Intelligent Surgical Instruments and build the infrastructure necessary to support our anticipated sales growth. We have financed our operations primarily through private placements of our equity securities and through the issuance of debt and, more recently, through our initial public offering in October 2007.

Key milestones in the development of our business include the following:

- In 1999 and 2000, we were a development stage enterprise primarily engaged in research and development. We developed key aspects of our core technology, including the basic architecture of our SurgASSIST surgical platform, filed our first patent applications and obtained FDA clearance to market the initial version of our SurgASSIST system.
- In 2001, we commenced the commercialization of our SurgASSIST platform. We contracted for the manufacture of key components and assembly of our SurgASSIST system by contract manufacturers. We began shipments of our SurgASSIST system, including our first four Intelligent Surgical Instruments, in June 2001. We generated \$2.1 million in sales in the last seven months of 2001.
- During 2002, 2003 and 2004, we expanded our SurgASSIST system by introducing six new Intelligent Surgical Instruments, including our lines of linear and right angle linear cutters and staplers. Our intellectual property portfolio was augmented by the issuance of 13 patents. We expanded our direct sales force and began to establish an international sales and distribution capability. Our sales increased from \$5.0 million in 2002 to \$7.2 million in 2003 and \$8.7 million in 2004.
- In 2005, we opened our current manufacturing facility in Langhorne, Pennsylvania and assumed responsibility for the assembly and testing of many of our products. We introduced our first

Intelligent Surgical Instruments designed specifically for use in minimally invasive surgery. We also began a series of research collaborations with key clinicians and hospitals intended to promote awareness and adoption of our SurgASSIST system. Our sales increased to \$12.0 million in 2005.

- In 2006, we continued to expand our suite of Intelligent Surgical Instruments, introducing new products, including a linear stapler designed for laparoscopic use and a circular stapler designed specifically for per-oral introduction. During 2006, our Intelligent Surgical Instruments were used in precedent-setting NOTES procedures, including what we believe were the first per-oral gastric bypass anastomosis and first per-oral esophagectomy.
- Sales in the first quarter of 2006 were consistent with 2005 levels in response to continuing demand for our products. However, we encountered supply chain and manufacturing difficulties in 2006 that adversely affected our sales for the last three quarters of the year:
  - the expansion of our manufacturing capacity in Langhorne, Pennsylvania disrupted our operations and reduced our manufacturing productivity during the first half of the year;
  - the commercial launch of our PLC 60 linear stapler was delayed by almost nine months due to product design and supply chain problems, and after we exhausted our inventory of the SLC 55 linear stapler that the new product was designed to replace, we were unable to provide linear staplers to the market for more than six months. Because linear staplers account for a majority of our unit sales, this resulted in a significant loss of sales; and
  - we were unable to ship another of our highest volume products, our RALC 45 right angle linear cutter, for approximately three months due to our failure to procure an adequate supply of the product.

Primarily as a result of these factors, our 2006 sales decreased to \$7.9 million and cost of sales was \$10.1 million, contributing to a loss from operations of \$27.6 million.

- We resumed shipments of the RALC 45 in November 2006 and introduced our PLC 60 linear stapler in late December 2006. However, sales attributable to our PLC 60 linear stapler were initially adversely affected by the limited availability of reload cartridges for the device. Demonstration units and sales collateral for the PLC 60 instrument were not fully available to our direct sales force until late in the first quarter of 2007. Also, during the first six months of 2007, we had limited inventory of the linear stapler products that the PLC 60 was intended to replace. We discontinued sales of the PLC 60 product in the fourth quarter of 2007 as a result of the introduction of our new i60 linear stapler.
- A key element of our business plan since our inception has been to incorporate the capabilities of our first-generation Intelligent Surgical Instruments in a new line of self-contained, unfettered devices that would eliminate the need for the power console, control unit and FlexShaft that are required for use of our first-generation products. During the fourth quarter of 2007, we introduced our i60 self-contained hand-held articulating linear stapler, the first of our next-generation products, and in December 2007 we received 510(k) marketing clearance for our iDrive self-contained wireless power and control system, which can be used to power and control our existing linear, right angle and circular staplers.

We make our i60 and iDrive instruments available without charge to our customers and depend on sales of the reload cartridges used in firing the instrument to generate revenue from this new product. During 2007 and the first quarter of 2008, we have experienced delays in the availability of green reload cartridges due to design and materials engineering problems. The unavailability of green reloads has resulted in lost revenue opportunities and slower than expected adoption of our next generation technology, as some surgeons and institutions are reluctant to employ the new instrument until reload

cartridges in both blue and green lengths are commercially available. We currently expect a redesigned green reload cartridge to be available in commercial quantities in the second quarter of 2008. Some early users of our i60 instrument have experienced difficulties, such as problems in consistently operating its articulation feature and in properly seating reload cartridges. Although these may in part be attributable to inadequate training or incorrect technique, they have led in some cases to a negative perception of product quality. Additionally, training of our sales force and the clinical personnel of our customers has taken longer than expected.

As a result of these factors, we are several months behind in our commercial launch plan for the i60 product. However, we expect to resolve these issues during the second quarter of 2008, and anticipate that reload sales will begin to grow more rapidly in the second half of 2008.

### **Financial Operations Overview**

The following is a description of the principal components of our sales and expenses and of significant trends and challenges that we believe are important to an understanding of our business and results of operations.

**Sales.** Our SurgASSIST surgical platform includes cutting and stapling devices in a variety of sizes and linear, right angle and circular configurations designed for differing surgical needs. In the original configuration of our system, our Intelligent Surgical Instruments are connected through a flexible shaft, or FlexShaft, to a power console. Our next generation products, beginning with the i60 linear stapler that we introduced in the fourth quarter of 2007, are self-contained hand-held instruments that do not require a FlexShaft or separate power console. In December 2007, we introduced our self-contained, wireless handheld iDrive system, which can be used to power and control our other linear, right angle and circular staplers, without the need for a separate FlexShaft or power console.

Our Intelligent Surgical Instruments are available as disposable, single-patient devices as well as in a reusable multiple-patient format, using disposable cutting and stapling cartridges in various sizes, which we refer to as reload cartridges.

Through 2007, most of our revenue has been derived from the sale of our single-patient, disposable Intelligent Surgical Instruments and, to a lesser extent, from the sale of reload cartridges for our reusable Intelligent Surgical Instruments. We expect that, as our installed base of reusable, multiple-patient Intelligent Surgical Instruments grows, sales of reload cartridges will become the largest component of our total sales.

We make power consoles and related accessories such as remote control units used with our first-generation SurgASSIST system available to institutions at no charge. We instituted a program in 2007 to make our PLC 60 instrument or FlexShaft available to the customer at no cost, in certain cases in exchange for a commitment by the customer to purchase a minimum number of reload cartridges at a higher unit price. We currently make our i60 and iDrive instruments available to customers at no charge, with the expectation that we will derive revenues from sales of the reload cartridges necessary for their use.

Our future success will depend on our ability to achieve and sustain significant growth in our sales. Our ability to grow our revenues will depend on many factors, including:

- continued growth in market acceptance of our SurgASSIST system;
- continued introduction of our next generation Intelligent Surgical Instruments on a timely basis;
- increased usage of our installed base of multiple-use Intelligent Surgical Instruments, resulting in recurring purchases of our reload cartridges;

- expansion of our sales and marketing organization and recruitment and retention of a sufficient number of qualified sales consultants;
- continued improvements in our supply chain and manufacturing operations to assure the quality and adequate supply of our products; and
- the availability of clinical data to substantiate the long term efficacy and safety of our products, which has not been collected to date.

*Cost of sales.* Cost of sales includes the cost of supplies, components and sub-assemblies that we purchase from third parties and use in the assembly of our products. Cost of sales also includes personnel costs and overhead related to our assembly and test operations, related occupancy, equipment depreciation, shipping costs and charges for inventory obsolescence.

Our future success will depend on our ability to make significant improvements in our cost of sales as a percentage of sales, or gross margins. Since the introduction of our SurgASSIST system in 2001, our gross margins have ranged from a negative gross margin of (56.9)% in 2002 to a positive gross margin of 14.5% for 2007. Our high cost of sales has been attributable to a number of factors, including product defects that have required rework by us and by our suppliers, a labor-intensive manual assembly process that has resulted in high labor costs, and excess manufacturing capacity in relation to our sales, which has resulted in inefficient absorption of manufacturing overhead.

Charges associated with write-offs of excess and obsolete inventory, which aggregated \$5.7 million between 2003 and 2006, have also contributed to our high cost of sales. Our product development plans sometimes include introductions of new products that overlap functionally with existing products, while offering new or improved capabilities. We anticipate that in some cases, this may lead to a reduction in demand for, or discontinuation of, an existing product. In these circumstances, we must carefully manage our finished goods inventory to ensure that we have quantities of the existing product that are sufficient to meet customer demand pending introduction of the new product, but that do not leave us holding excess or obsolete inventory when a new product supplants the existing one.

Historically, our cost of sales has included the substantial cost of our power consoles and related accessories, which had a significant adverse effect on our gross margins. We decided in 2005 that it would facilitate market acceptance of our Intelligent Surgical Instruments to make the power consoles and certain related accessories necessary for the use of our Intelligent Surgical Instruments available to institutions in appropriate circumstances at no charge. In light of this change in our business strategy, we recorded a charge to write down the value of our inventory of power consoles to their net realizable value, and the resulting \$2.4 million charge significantly increased our cost of sales in 2005. We now include in cost of sales depreciation expense for power consoles and related accessories loaned to customers for their use at no charge. The cost of the i60 and iDrive instruments that we currently make available to customers at no charge is recorded as a charge to cost of sales when the units are shipped to the customer.

In order to achieve and sustain profitability, we will need to devote substantial resources to improving our procurement and manufacturing processes, upgrading our management information systems, and implementing new quality assurance, inventory and cost controls in order to reduce the cost of the components we purchase from third party vendors and improve the efficiency of our manufacturing operations. We also intend to increase the integration of our manufacturing operations, for example, by acquiring the capital equipment necessary to enable us to more efficiently assemble critical components such as the reload cartridges that are used in our reusable multiple-patient linear staplers. We believe this will enable us to significantly reduce the cost of these components, while also enabling us to better control their supply and quality. However, we cannot assure you that manufacturing yields or costs will not be adversely affected, at least initially, by the transition to in-house production or to new production processes. Because we have limited experience in

manufacturing our products in commercial quantities, increasing our manufacturing capacity to support our planned sales growth while significantly improving our gross margins and maintaining product quality will involve significant challenges. The recent departure of our chief operations officer may, in the near term, increase these challenges, as his successor may require a period of transition to become familiar with our operations.

*Research and development expenses.* Research and development expenses consist primarily of salaries and related expenses and overhead for our research, development and engineering personnel, prototype materials and research studies. We expense our research and development costs as incurred.

Our research and development expenses have fluctuated significantly in dollar amount and as a percentage of sales in the last five years, due primarily to the timing of research and development efforts associated with significant new product introductions. We anticipate that our research and development expenses will increase as we continue to invest in the development of new products and technologies.

*Sales and marketing expenses.* Sales and marketing expenses consist primarily of salaries and related expenses, sales commissions and overhead for personnel performing sales and marketing functions. Other significant sales and marketing expenses include travel and entertainment expense, costs of attending medical conferences and trade shows, clinician training and other promotional costs and costs of demonstration systems and samples.

Our sales and marketing expenses have substantially exceeded our sales in each year since 2004, as we have invested in building the sales and marketing organization and administrative infrastructure necessary to support our planned sales growth. During the first quarter of 2008, we have taken steps to reduce our sales and marketing expenses through a reduction in the number of our direct sales personnel, and as a result we do not expect these expenses to grow in 2008 at the same rate they have in recent years.

*General and administrative expenses.* General and administrative expenses consist primarily of salaries and related expenses and overhead for personnel performing executive, finance, information technology and human resource functions. Other significant general and administrative expenses include consulting fees and professional fees for legal services (including services related to obtaining and maintaining protection of our intellectual property) and accounting services.

*Interest income.* Interest income consists of interest earned on our cash and cash equivalents.

*Interest expense.* Interest expense consists of interest expense on our revolving line of credit, term loans, bridge financing and equipment loans.

### **Internal Control over Financial Reporting**

Our management has determined that we have a material weakness in our internal control over financial reporting related to our financial statement close process that, until remediated, results in a reasonable possibility that a material misstatement to the annual or interim consolidated financial statements could occur and not be prevented or detected by our internal controls in a timely manner. We have concluded that there is a material weakness in our internal control over financial reporting because we do not have a sufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve non-routine and complex accounting matters or to evaluate the impact of new and existing accounting pronouncements on our consolidated financial statements while completing the financial statement close process. The material weakness resulted in the identification of adjustments during the financial statement close process during 2007 that have been



recorded in the consolidated financial statements. In order to remediate this material weakness, we are taking the following actions:

- we are actively seeking additional accounting and finance staff members to augment our current staff and to improve the effectiveness of our financial statement close process; and
- we are expanding the training and education of our accounting and finance staff members in an effort to improve their effectiveness.

Notwithstanding the material weakness that existed as of December 31, 2007, our management has concluded that the consolidated financial statements included elsewhere in this report present fairly, in all material respects, our financial position, results of operation and cash flows in conformity with U.S. generally accepted accounting principles.

### **Backlog**

Our sales in any period are dependent primarily on orders booked and shipped in that period. As a result, we do not currently consider backlog to be an important indicator of sales for any future period. At December 31, 2007, our firm backlog, which consists of all accepted purchase orders for which our customer has specified a delivery date within the next twelve months, was \$109,000 compared with \$331,000 at December 31, 2006. We expect that in the longer term, as sales of reload cartridges become a more significant element of our business, backlog may become a more meaningful indicator of future sales.

### **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. These estimates and judgments are inherently subject to uncertainty. On an ongoing basis, we re-evaluate our judgments and estimates, including those related to uncollectible accounts receivable, inventories, recoverability of long-lived assets, stock-based compensation, accrued expenses and other contingencies. We base our estimates and judgments on our historical experience and on other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making the judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates, and material effects on our operating results and financial position could result. The accounting policies described below are those which, in our opinion, involve the most significant application of judgment, or involve complex estimation, and which could, if different judgments or estimates were made, materially affect our reported results of operations.

*Revenue recognition.* Most of our revenue has been derived from the sale of our single-patient, disposable Intelligent Surgical Instruments and from the sale of reload cartridges for our reusable Intelligent Surgical Instruments. Revenue related to the sale of such individual products is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the sale price is fixed and determinable, and collectibility is reasonably assured, which is generally at the time of shipment upon delivery to a common carrier.

Historically, we derived a limited amount of revenue from the sale of complete SurgASSIST systems, consisting of one or more Intelligent Surgical Instruments, together with the related power console, FlexShaft and remote control unit. Revenue related to the sale of a complete SurgASSIST system is recognized at the time of shipment upon delivery to a common carrier. Sales of these complete systems have not been significant during any period presented.

We have generally provided power consoles, FlexShafts, remote control units and mobile carts associated with our first-generation SurgASSIST system to customers at no cost as loaner equipment. In certain cases, we have agreed to transfer title to such systems to the customer upon the customer's purchase of a specified number of disposable Intelligent Surgical Instruments, although the customer is under no obligation to purchase the Intelligent Surgical Instruments. In these instances, we recognize revenue attributable to the complete system as the Intelligent Surgical Instruments are delivered, in accordance with EITF 00-21, *Revenue Arrangements with Multiple Deliverables*.

In 2007, we instituted a program whereby we provided our first-generation Intelligent Surgical Instruments and FlexShafts to customers at no cost. In certain cases, we offer such Intelligent Surgical Instruments and FlexShafts at no cost in exchange for higher unit pricing on the sale of reload cartridges over a specified period of time. In these cases, we recognize the revenue ratably over the period of delivery of the reload cartridges in accordance with the guidance of EITF 00-21, as long as such revenue is not contingent on the delivery of the undelivered products. In addition, we currently make our i60 and iDrive instruments available to customers at no charge and without conditions. We recognize revenue related to reload cartridges for such instruments as such reload cartridges are delivered.

Our customers generally order product using standard purchase orders, and payment terms are 30 days. We provide discounted pricing to our customers based on volume and commitment levels. Allowance for product returns are estimated based on historical experience, and provisions are recorded at the time of shipment. We also provide limited warranties to our customers against material defects in materials and workmanship. Such warranties are generally for a one year period from the date of the shipment. Historically, warranty costs have not been material.

*Allowance for doubtful accounts.* We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of some of our customers to make required payments. The allowance for doubtful accounts is based on the specific identification of customer accounts that are overdue and for which management has estimated the expectation of actual loss.

*Inventories.* Inventories are valued at the lower of cost or market value. Cost is determined on a first-in, first-out method. Costs include direct materials, direct labor and applicable manufacturing overhead, and other direct costs. We assess the valuation of our inventory on a periodic basis and write down the value for estimated excess and obsolete inventory based on estimates of future demand. We define obsolete inventory as inventory that will no longer be used in our manufacturing processes. Excess inventory is defined as inventory in excess of projected usage and is determined using management's best estimate of future demand, based upon information then available to us.

*Long-lived assets.* Intangible assets with definite lives are amortized using the straight-line method and consist mainly of patents. We follow Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, to evaluate impairment of intangible assets subject to amortization and other long-lived assets. We periodically evaluate whether current facts or circumstances indicate that the carrying value of such assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the fair value using quoted market prices in active markets, if available. If quoted market prices are not

available, the estimate of fair value is based on various valuation techniques, including the discounted value of estimated future cash flows.

*Stock-based compensation.* Prior to 2006, we accounted for our stock-based compensation plans in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25) and the related interpretations. Under APB 25, no compensation expense was recognized if the exercise price of our stock options equaled or exceeded the fair value of the underlying common stock at the date of grant. We provided pro forma disclosures in our financial statements as required by SFAS 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*, related to these fiscal periods prior to January 1, 2006.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and supersedes APB 25. SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first annual period after December 15, 2005. SFAS No. 123(R) requires that an entity measure the fair value of equity-based service awards at the grant date and recognize the cost of such award over the period during which the employee is required to provide service in exchange for the award (vesting period). The pro forma disclosures previously permitted under SFAS No. 123 are no longer an alternative to financial statement recognition.

We adopted SFAS No. 123(R) on January 1, 2006 using the prospective transition method, which required that all new stock-based awards granted subsequent to adoption be recognized in the financial statements at fair value. We account for equity issued to non-employees in accordance with EITF 96-18, *Accounting for Equity Investments that are Issued to Other Than Employees for Acquiring, or in Conjunction with, Selling Goods or Services* (EITF 96-18).

In connection with the preparation of the financial statements included in this report, we retrospectively analyzed the fair value of our common stock at various option grant dates during 2006 and prior to our initial public offering in October 2007. For that purpose, in early 2007 we engaged an unrelated valuation firm, The Baker-Meekins Company, Inc., which we refer to as Baker-Meekins, to provide its opinion as to the fair value per share of our common stock as of stated dates in 2006 and 2007 prior to our initial public offering in October 2007. In performing its analysis, Baker-Meekins used valuation methodologies consistent with the requirements of AICPA Technical Practice Aid, *Valuation of Privately Held Company Equity Securities Issued as Compensation*. Specifically, Baker-Meekins considered the following methodologies in arriving at its opinion as to the fair value of our common stock:

- analysis of the implied value of our company based upon purchases of our equity securities by unrelated investors;
- an estimate of the value of our company using a discounted cash flow analysis, based upon the present value of anticipated future cash flows, discounted at an appropriate discount rate reflecting the risk inherent in the investment; and
- allocation of our company's equity value, as determined by reference to the above analyses, to our outstanding classes of equity securities using the option pricing method.

Baker-Meekins concluded, in its valuation report dated March 6, 2007, and updated by a supplemental report dated April 5, 2007, that the fair value of our common stock at the stated dates ranged from \$4.48 per share to \$7.68 per share during 2006, and was \$7.68 per share in the second quarter of 2007.

Since the closing of our initial public offering in October 2007, we have utilized the quoted market price on the date of grant as the fair market value of our common stock within our Black-Scholes option pricing model.

Based on these estimates of the fair value of our common stock, we estimated that the per-share weighted average fair value of the options granted during 2007 and 2006 was \$5.42 in 2007 and \$4.16 in 2006, using the Black-Scholes option-pricing model with the following weighted average assumptions, which are based upon company history or industry comparative information:

	Year ended December 31, 2007	Year ended December 31, 2006
Expected dividend yield .....	0%	0%
Expected volatility .....	58%	65%
Risk-free interest rates .....	4.40%	4.70%
Expected life .....	7 years	7 years

The expected volatility was calculated for each date of grant based on an alternative method (defined as "calculated value"). We identified similar public entities for which share price information is available and have considered the historical volatility of these entities' share prices in estimated expected volatility. We used the average volatility of these guideline companies over a seven-year period, consistent with the expected term calculated pursuant to Staff Accounting Bulletin No. 107.

Compensation expense under SFAS No. 123(R) and EITF 96-18 for the year ended December 31, 2007 related to share-based service awards and performance based grants granted in 2007 and 2006 was \$1,010,664, of which \$5,063 is included in cost of sales, \$92,511 is included in sales and marketing, \$28,958 is included in research and development and \$884,132 is included in general and administrative expense in the accompanying consolidated statements of operations. We recognize the compensation expense of such share-based service awards on a straight-line basis. Total compensation cost of options granted but not yet vested as of December 31, 2007, exclusive of a performance grant to an executive officer in the second quarter of 2007, was \$2,384,483, net of estimated forfeitures, which we expect to recognize over the weighted average period of 2.3 years. Compensation expense under SFAS No. 123(R) and EITF 96-18 for the year ended December 31, 2006 related to share-based service awards granted in 2006 was \$190,105, of which \$1,193 is included in cost of sales, \$40,923 is included in sales and marketing and \$147,989 is included in general and administrative expense in the accompanying consolidated statements of operations. We utilized an estimated forfeiture rate of 15% for their 2006 and 2007 grants, based on our historical forfeiture rate as well as an analysis of current market conditions.

## Results of Operations

The following table sets forth, for the periods indicated, selected statement of operations data:

	Year Ended December 31,		
	2007	2006	2005
	(in thousands)		
Sales .....	\$ 7,812	\$ 7,881	\$ 11,999
Cost of sales .....	6,676	10,066	12,346
Gross profit .....	1,136	(2,185)	(347)
<b>Costs and expenses:</b>			
Research and development .....	6,209	4,682	5,482
Sales and marketing .....	19,703	13,367	14,630
General and administrative .....	9,959	7,371	6,331
Loss from operations .....	(34,735)	(27,605)	(26,790)
<b>Other income (expense):</b>			
Interest income .....	866	544	270
Interest expense .....	(2,976)	(1,269)	(916)
<b>Total other income (expense) .....</b>	<b>(2,110)</b>	<b>(725)</b>	<b>(646)</b>
Net loss .....	<u><u>\$(36,845)</u></u>	<u><u>\$(28,330)</u></u>	<u><u>\$(27,436)</u></u>

The following table sets forth, for the periods indicated, selected statement of operations data expressed as a percentage of our sales:

	Year Ended December 31,		
	2007	2006	2005
	(in thousands)		
Sales .....	100.0%	100.0%	100.0%
Cost of sales .....	85.5	127.7	102.9
Gross profit .....	14.5	(27.7)	(2.9)
<b>Costs and expenses:</b>			
Research and development .....	79.5	59.4	45.7
Sales and marketing .....	252.2	169.6	121.9
General and administrative .....	127.5	93.5	52.8
Loss from operations .....	(444.7)	(350.2)	(223.3)
<b>Other income (expense):</b>			
Interest income .....	11.1	6.9	2.3
Interest expense .....	(38.1)	(16.1)	(7.6)
<b>Total other income (expense) .....</b>	<b>(27.0)</b>	<b>(9.2)</b>	<b>(5.3)</b>
Net loss .....	<u><u>(471.7)%</u></u>	<u><u>(359.4)%</u></u>	<u><u>(228.6)%</u></u>

### Year ended December 31, 2007 compared to year ended December 31, 2006

**Sales.** Our sales decreased by 0.9%, from \$7.9 million in 2006 to \$7.8 million in 2007. The decrease was the result of the limited availability of our reload cartridges for the PLC 60 product during 2007 and our decision to stop selling our PLC 60 product in the third quarter of 2007 in anticipation of the launch of our new i60 linear stapler which occurred in September 2007.

**Cost of sales and gross profit.** Our cost of sales decreased by 33.7%, from \$10.1 million in 2006 to \$6.7 million in 2007, and our gross profit increased from a negative gross profit of \$2.2 million, or

(27.7)% of sales, in 2006 to \$1.1 million, or 14.5% of sales, in 2007. The gross margin improvements reflect the benefits of switching from contract manufacturing to self manufacturing for certain of our products, increased efficiencies of our manufacturing operations and, to a lesser extent, lower charges for inventory obsolescence in 2007. Our gross margins may experience fluctuations from period to period until we are able to realize further economies of scale in our purchasing and manufacturing process.

*Research and development expenses.* Our research and development expenses increased by 32.6%, from \$4.7 million in 2006 to \$6.2 million in 2007. The increase was due primarily to an increase of \$0.8 million in our prototype, component and validation costs associated with the introduction of our i60 and iDrive products during 2007 and to an increase of \$0.5 million in compensation and related costs due to increased headcount in our research and development staff.

*Sales and marketing expenses.* Our sales and marketing expenses increased by 47.4%, from \$13.4 million in 2006 to \$19.7 million in 2007. The increase was due to the planned rapid growth of our domestic and international sales force, which resulted in higher compensation and recruiting costs. In addition, we incurred approximately \$1.4 million of sales sample expense associated with placing the recently approved i60 and iDrive instruments with the larger sales force.

*General and administrative expenses.* Our general and administrative expenses increased by 35.1%, from \$7.4 million in 2006 to \$10.0 million in 2007. The increase is the result of higher stock-based compensation expense of approximately \$0.7 million during 2007, increased costs associated with becoming a public company in the fourth quarter of 2007 and increased compensation and related costs due to increased headcount in our executive management staff.

*Interest income.* Our interest income increased 59.3%, from \$0.5 million in 2006 to \$0.9 million in 2007, as a result of our higher cash balances during 2007.

*Interest expense.* Our interest expense increased by 134.6%, from \$1.3 million in 2006 to \$3.0 million in 2007. The increase was the result of higher indebtedness during 2007, primarily related to our \$25.0 million of convertible notes issued in March 2007.

#### **Year ended December 31, 2005 compared to year ended December 31, 2006**

*Sales.* Our sales decreased by 34.3%, from \$12.0 million in 2005 to \$7.9 million in 2006. The decrease was largely the result of our inability to fulfill demand for our products on a timely basis in the last three quarters of 2006, due primarily to manufacturing and supply chain problems that affected the availability of our RALC 45 right angle linear cutter and delays in the introduction of our PLC 60 linear stapler, which resulted in cancellation and postponement of orders and the loss of significant sales opportunities.

*Cost of sales and gross profit.* Our cost of sales decreased by 18.5%, from \$12.3 million in 2005 to \$10.1 million in 2006, but increased as a percentage of sales. Our gross profit decreased from a loss of \$347,000, or 2.9% of sales, in 2005 to a loss of \$2.2 million, or 27.7% of sales in 2006. The decrease in dollar amount was attributable primarily to the lower volume of product sales in 2006. The decrease in our gross profit and our gross margin percentage was attributable to inefficiencies associated with the start up of our manufacturing facility.

*Research and development expenses.* Our research and development expenses decreased by 14.6%, from \$5.5 million in 2005 to \$4.7 million in 2006, but increased as a percentage of sales from 45.7% in 2005 to 59.4% of sales in 2006. The decrease in dollar amount was due to expense control measures that we instituted in response to our declining sales, offset in part by increased costs of prototypes for our new PLC 60 product. The increase as a percentage of sales was due to our reduced sales.

*Sales and marketing expenses.* Our sales and marketing expenses decreased by 8.6%, from \$14.6 million in 2005 to \$13.4 million in 2006, but increased as a percentage of sales from 121.9% of sales in 2005 to 169.6% of sales in 2006. The decrease in dollar amount was due primarily to lower sales commissions of approximately \$774,000 due to a decrease in sales and a decrease in recruiting costs of approximately \$175,000 due to a reduction in the number of new hires of sales personnel, which was partly offset by stock-based compensation of \$41,000 in 2006 as a result of our adoption of SFAS 123(R). The increase as a percentage of sales was due to our reduced sales.

*General and administrative expenses.* Our general and administrative expenses increased by 16.4%, from \$6.3 million in 2005 to \$7.4 million in 2006, and increased as a percentage of sales from 52.8% of sales in 2005 to 93.5% of sales in 2006. The increase in dollar amount was due primarily to an increase in legal fees of \$258,000, an increase in accounting fees of \$195,000, an increase in depreciation expense of \$294,000, and an increase in recruiting expense of \$94,000. In addition, we recorded stock-based compensation of \$148,000 in 2006 as a result of our adoption of SFAS 123(R). These increases were offset by a decrease in rent expense of \$189,000.

*Interest income.* Interest income increased by 101.3%, from \$270,000 in 2005 to \$544,000 in 2006, primarily as a result of higher cash balances attributable to a private placement of our convertible preferred stock in August 2006.

*Interest expense.* Interest expense increased by 38.5%, from \$916,000 in 2005 to \$1.3 million in 2006 as a result of increased borrowing, including bridge debt financing that preceded our private placement of preferred stock in 2006.

#### **Liquidity and Capital Resources**

Since our inception, we have financed our operations primarily through private placements of our redeemable preferred stock, unsecured borrowings from our stockholders, a credit facility and, more recently, the issuance in March 2007 of our convertible notes in the aggregate principal amount of \$25.0 million, and our initial public offering in October 2007, which generated net proceeds of \$42.0 million. Our principal source of liquidity as of December 31, 2007 consisted of our cash and cash equivalents of \$36.6 million and our accounts receivable balance of \$1.5 million.

In 2007, our operating activities used \$32.0 million in cash, due primarily to our net operating loss of \$36.8 million. We used cash of \$0.7 million for prepaid expenses and other assets, and \$2.9 million for inventory, primarily raw materials and components required for assembly of our PLC 60, i60 and iDrive instruments and reload cartridges, which we have increasingly assembled ourselves rather than purchasing them as completed products from contract manufacturers. These uses were partially offset by a \$1.8 million increase in accounts payable due to an overall increase in business expenses of the company, and a \$2.5 million increase in accrued expenses, primarily related to interest expense related to our issuance of convertible notes in March 2007 and an overall increase in purchases in the fourth quarter of 2007. Our non-cash expenses of approximately \$4.0 million included depreciation and amortization of \$2.4 million and stock-based compensation of \$1.0 million. We used \$5.6 million in our investing activities, primarily consisting of purchases of property and equipment of \$2.0 million and an increase in restricted cash of \$3.2 million, attributable to interest payments required to be deposited in escrow pursuant to our convertible note agreements and approximately \$0.7 million related to a bank guarantee we furnished as a condition to obtaining a stay of enforcement in our pending patent litigation in Germany. Our financing activities provided \$65.8 million of cash, including \$23.3 million of net proceeds from the issuance of our convertible notes, and \$42.6 million from the issuance of common stock, primarily from our initial public offering.

In 2006, our operating activities used \$24.7 million in cash, due to our net operating loss of \$28.3 million, which was partly offset by a net positive change in our operating assets and liabilities of

\$1.1 million, which was primarily due to a \$1.8 million reduction in inventory, attributable to a deliberate effort by us to reduce our inventory levels in 2006 as well as to the exhaustion by the end of 2006 of our inventory of SLC 55 and PLC 75 products, and to a \$0.6 million increase in accrued compensation and other accrued expenses. These changes more than offset a \$1.3 million use of cash to reduce our accounts payable during 2006 as a result of more restrictive payment terms required by some of our vendors, many of whom were new suppliers with which we had not yet established a credit history. We have generally experienced more favorable credit terms in 2007. We incurred non-cash expenses of \$2.0 million for depreciation and amortization. Other significant non-cash expense items included \$0.2 million of stock-based compensation expense as a result of our adoption during 2006 of SFAS 123(R). We also used \$1.6 million in our investing activities, primarily consisting of purchases of property and equipment of \$1.4 million. Our financing activities provided \$27.2 million of cash, including \$37.2 million of net proceeds from the issuance of preferred stock, warrants and bridge loans, offset in part by our repayment of long-term debt and capital leases of \$10.1 million.

We believe that our cash and cash equivalents will be sufficient to meet our anticipated cash requirements through at least January 1, 2009, however, there can be no assurance in this regard. If necessary, we have the intent and ability to reduce spending in 2008 by controlling costs that are within management's discretion. Such costs include certain sales and marketing costs, clinical research costs, employee bonuses, professional education, and capital expenditures. Our future cash requirements will depend on many factors, including our rate of sales growth, if any, the timing and extent of spending to support new product development efforts, the expansion of our sales and marketing activities, the timing and introductions of new products and the amount and timing of capital investments we make and cost we incur to expand our manufacturing capacity. Our ability to meet our obligations in the normal course of business beyond January 1, 2009 will be dependent on our increasing our customer and revenue base, controlling expenses and securing additional external financing. We have made no arrangements to obtain additional financing, and there can be no assurance that such financing, if required or desired, will be available in amounts or on terms acceptable to us, if at all. These conditions raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm has modified its audit report on our consolidated financial statements to include an explanatory paragraph regarding this contingency.

#### Contractual Obligations

Set forth below is information concerning our known contractual obligations as of December 31, 2007.

	Payments Due by Period (in thousands)				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
<b>Contractual Obligations</b>					
Long-term debt(1) .....	\$30,800	\$1,829	\$28,808	\$ 157	\$ 7
Operating leases .....	3,060	721	1,445	894	—
<b>Total .....</b>	<b>\$33,860</b>	<b>\$2,550</b>	<b>\$30,253</b>	<b>\$1,051</b>	<b>\$ 7</b>

- (1) Includes payments due to the holders of our convertible notes issued in March 2007. The \$25.0 million principal amount of our convertible notes is due in March 2010. Interest is payable semi-annually in arrears. In March 2007, we deposited in escrow cash in an amount sufficient to pay the first four semi-annual interest payments. Of the payments for long-term debt identified above, the escrow deposit will fund \$1.8 million of the amount due within less than one year, and \$0.9 million of the amount due within one to three years.



## **Recent Accounting Pronouncements**

*FIN 48.* In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We adopted FIN 48 on January 1, 2007. The adoption did not have a material impact on our consolidated financial statements.

We do not believe that there are any other recently issued but not yet effective accounting pronouncements that, if adopted by us, would have a material effect on the accompanying financial statements.

### **Item 7A. *Quantitative and Qualitative Disclosures about Market Risk.***

We are exposed to market risk in the ordinary course of business, which consists primarily of interest rate risk associated with our cash and cash equivalents and debt and foreign exchange rate risk.

*Interest rate risk.* The primary objective of our investment activity is to preserve principal, provide liquidity and maximize income without increasing risk. Our investments have limited exposure to market risk. To minimize this risk, we maintain our portfolio of cash and cash equivalents in a variety of investments, consisting primarily of bank deposits, money market funds and short-term government funds. The interest rates are variable and fluctuate with current market conditions. The risk associated with fluctuating interest rates is limited to this investment portfolio, and we do not believe that a 10% change in interest rates would have a material impact on our financial position or results of operations.

The interest rate on our convertible notes is currently fixed and therefore exposes us to limited market risk.

*Foreign currency risk.* To date, our international customer agreements have been denominated primarily in the local currency of the international customer. The functional currency of our foreign operations in Europe and Japan is the local currency and, as a result, any fluctuation in the exchange rates of these net assets, denominated in local currency, would be reflected in the translation gains or losses, which are accounted for in other comprehensive income in our statements of changes in equity. We do not believe that a change of 10% in the foreign currency exchange rates would have a material impact on our financial position or results of operations.

**Item 8. *Financial Statements and Supplementary Data.***

**Power Medical Interventions, Inc.  
Index To Consolidated Financial Statements  
Contents**

Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006 .....	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005 .....	F-4
Consolidated Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity (Deficit) for the years ended December 31, 2007, 2006 and 2005 .....	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 .....	F-6
Notes to Consolidated Financial Statements .....	F-7

## **Report of Independent Registered Public Accounting Firm**

The Board of Directors and Shareholders  
Power Medical Interventions, Inc.

We have audited the accompanying consolidated balance sheets of Power Medical Interventions, Inc. as of December 31, 2007 and 2006, and the related consolidated statements of operations, redeemable convertible preferred stock and shareholders' equity (deficit), and cash flows for each of the three years in the period ended December 31, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Power Medical Interventions, Inc. at December 31, 2007 and 2006, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2007, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that Power Medical Interventions, Inc. will continue as a going concern. As more fully described in Note 1, the Company has an accumulated deficit and has continued to incur operating losses. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The 2007 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

As discussed in Note 2 to the consolidated financial statements, Power Medical Interventions, Inc. changed its method of accounting for stock-based compensation in accordance with Statement of Financial Accounting Standards No. 123 (revised 2004) on January 1, 2006.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania  
March 21, 2008,

**Power Medical Interventions, Inc.**  
**Consolidated Balance Sheets**

	December 31	
	2007	2006
<b>Assets</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 36,592,220	\$ 8,684,341
Restricted cash . . . . .	1,750,000	—
Accounts receivable less allowance of \$120,000 and \$173,000 in 2007 and 2006 respectively . . . . .	1,514,776	1,654,815
Inventory . . . . .	7,371,205	4,475,693
Prepaid expenses and other current assets . . . . .	1,178,493	497,959
Deferred equity offering costs . . . . .	—	51,807
Total current assets . . . . .	48,406,694	15,364,615
Property and equipment, net . . . . .	4,713,010	4,871,450
Intangibles, net . . . . .	965,303	757,894
Deferred financing fees . . . . .	1,276,010	—
Other assets . . . . .	261,862	268,569
Restricted cash . . . . .	2,350,071	879,310
Total assets . . . . .	<u>\$ 57,972,950</u>	<u>\$ 22,141,838</u>
<b>Liabilities and shareholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 4,422,198	\$ 2,582,196
Accrued expenses . . . . .	4,506,748	2,172,459
Current portion of long-term debt . . . . .	69,230	75,610
Total current liabilities . . . . .	8,998,176	4,830,265
Long-term debt, net of current portion . . . . .	24,742,891	376,826
Deferred rent, net of current portion . . . . .	691,873	765,918
Total liabilities . . . . .	34,432,940	5,973,009
<b>Redeemable convertible preferred stock, \$.001 par value:</b>		
Series A—authorized, issued and outstanding shares—22,668,764 at December 31, 2006 . . . . .	—	18,244,492
Series B—authorized, issued and outstanding shares—47,489,822 at December 31, 2006 . . . . .	—	42,893,061
Series C—authorized shares—22,935,780 at December 31, 2006; issued and outstanding shares—21,223,750 at December 31, 2006 . . . . .	—	17,789,085
Series D—authorized shares—50,954,779; issued and outstanding shares—50,596,158 at December 31, 2006 . . . . .	—	37,271,570
Total redeemable convertible preferred stock . . . . .	—	116,198,208
<b>Shareholders' equity (deficit):</b>		
Common stock, \$.001 par value:		
Authorized shares—200,000,000 and 260,000,000 at December 31, 2007 and December 31, 2006, respectively; issued and outstanding shares—17,107,052 and 3,757,755 at December 31, 2007, and December 31, 2006, respectively . . . . .	17,107	3,758
Additional paid-in capital . . . . .	197,733,981	37,188,432
Accumulated other comprehensive loss . . . . .	(300,184)	(155,533)
Accumulated deficit . . . . .	(173,910,894)	(137,066,036)
Total shareholders' equity (deficit) . . . . .	23,540,010	(100,029,379)
Total liabilities, redeemable convertible preferred stock, and shareholders' equity (deficit) . . . . .	<u>\$ 57,972,950</u>	<u>\$ 22,141,838</u>

*See notes to consolidated financial statements.*

**Power Medical Interventions, Inc.**  
**Consolidated Statements of Operations**

	Year Ended December 31		
	2007	2006	2005
<b>Sales</b> .....	\$ 7,812,055	\$ 7,881,210	\$ 11,998,676
<b>Cost of sales</b> .....	6,675,598	10,066,218	12,345,617
	<u>1,136,457</u>	<u>(2,185,008)</u>	<u>(346,941)</u>
<b>Costs and expenses:</b>			
Research and development .....	6,208,962	4,682,220	5,482,311
Sales and marketing .....	19,703,140	13,367,378	14,629,572
General and administrative .....	9,959,390	7,371,190	6,331,015
	<u>35,871,492</u>	<u>25,420,788</u>	<u>26,442,898</u>
Operating loss .....	(34,735,035)	(27,605,796)	(26,789,839)
<b>Other income (expense):</b>			
Interest income .....	866,173	543,853	270,204
Interest expense .....	(2,975,996)	(1,268,496)	(916,460)
<b>Total other income (expense)</b> .....	<u>(2,109,823)</u>	<u>(724,643)</u>	<u>(646,256)</u>
Net loss .....	\$(36,844,858)	\$(28,330,439)	\$(27,436,095)
Accretion of preferred stock .....	(7,549,776)	(7,108,267)	(4,808,425)
Net loss applicable to common shares .....	\$(44,394,634)	\$(35,438,706)	\$(32,244,520)
<b>Net loss per common share:</b>			
Basic and diluted .....	<u>\$ (7.34)</u>	<u>\$ (9.44)</u>	<u>\$ (8.90)</u>
<b>Weighted average number of common shares outstanding:</b>			
Basic and diluted .....	<u>6,047,699</u>	<u>3,755,709</u>	<u>3,621,069</u>

*See notes to consolidated financial statements.*

**Power Medical Interventions, Inc.**

**Stockholders' Equity (Deficit)**

See notes to consolidated financial statements.

**Power Medical Interventions, Inc.**  
**Consolidated Statements of Cash Flows**

	Year ended December 31,		
	2007	2006	2005
<b>Operating activities</b>			
Net loss	\$(36,844,858)	\$(28,330,439)	\$(27,436,095)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,407,583	1,971,876	1,388,390
Amortization of debt discount and deferred financing fees	612,141	270,369	14,246
Loss on the disposal of property and equipment	3,492	60,894	12,556
Stock-based compensation	1,010,664	211,705	—
Changes in operating assets and liabilities:			
Accounts receivable	161,345	73,918	(351,496)
Inventory	(2,852,898)	1,823,790	(1,702,895)
Prepaid expenses and other assets	(658,654)	(1,769)	(502,685)
Accounts payable	1,753,999	(1,317,607)	1,555,578
Accrued expenses	2,456,858	576,371	(199,927)
Deferred rent	(74,045)	(78,963)	826,016
Net cash used in operating activities	(32,024,373)	(24,739,855)	(26,396,312)
<b>Investing activities</b>			
Proceeds from disposal of assets	—	6,000	—
Purchase of property and equipment	(2,022,903)	(1,449,621)	(4,699,466)
Patent application costs	(399,542)	(252,265)	(276,292)
Change in restricted cash	(3,220,897)	140,960	—
Net cash used in investing activities	(5,643,342)	(1,554,926)	(4,975,758)
<b>Financing activities</b>			
Repayments on long-term debt	(79,927)	(10,067,914)	(12,500,000)
Proceeds of long-term debt, net	23,298,654	—	10,520,350
Principal payments on capital lease obligations	—	(12,353)	(33,278)
Net proceeds from the issuance of preferred stock, warrants, and bridge loans	—	37,236,510	16,534,482
Net proceeds from the issuance of common stock and exercise of common stock warrants and options	42,619,479	5,459	3,469,870
Net cash provided by financing activities	65,838,206	27,161,702	17,991,424
Effect of exchange rate changes on cash and cash equivalents	(262,612)	(115,181)	(318,725)
Net increase (decrease) in cash and equivalents	27,907,879	751,740	(13,699,371)
Cash and cash equivalents, beginning of period	8,684,341	7,932,601	21,631,972
Cash and equivalents, end of period	<u>\$ 36,592,220</u>	<u>\$ 8,684,341</u>	<u>\$ 7,932,601</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	<u>\$ 895,926</u>	<u>\$ 1,104,108</u>	<u>\$ 987,281</u>
<b>Supplemental disclosure of non-cash investing activities:</b>			
Transfer of equipment from inventory to property, plant and equipment	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 456,374</u>

*See notes to consolidated financial statements.*

**Power Medical Interventions, Inc.**  
**Notes to Consolidated Financial Statements**  
**December 31, 2007**

**1. Business**

Power Medical Interventions, Inc. (the Company), a Delaware corporation, is a medical device company that designs, manufactures and markets the SurgASSIST® system of computer-assisted, power-actuated endomechanical surgical instruments, referred to as Intelligent Surgical Instruments™. Surgeons use Intelligent Surgical Instruments for cutting, stapling and tissue manipulation in a variety of procedures in open surgery, minimally invasive surgery, or MIS, and in the emerging field of natural orifice transluminal endoscopic surgery, or NOTES. To date, the majority of the Company's efforts have been devoted to research and development, raising capital, recruiting personnel, and the commercialization of products and the commencement of manufacturing activities.

The Company has wholly owned subsidiaries in Germany, Power Medical Interventions Deutschland GmbH; in France, Power Medical Interventions France; and in Japan, Power Medical Interventions Japan, which conduct sales and marketing operations. The Company also has a dormant U.S. subsidiary, Power Medical Vascular, Inc.

The consolidated financial statements of the Company have been prepared on a going-concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. Accordingly, the financial statements do not include any adjustments that might be necessary should the Company be unable to continue in existence. The Company incurred net losses of \$36,844,858, \$28,330,439, and \$27,436,095 for the years ended December 31, 2007, 2006 and 2005, respectively, and has an accumulated deficit of \$173,910,894 at December 31, 2007. Losses are expected to continue at least through 2008. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management believes that actions presently being taken will provide for the Company to continue as a going concern through at least January 1, 2009, however there can be no assurance in this regard. Such actions include the reduction of spending during 2008 by controlling costs that are within management's discretion. Such costs include certain sales and marketing costs, clinical research costs, employee bonuses, professional education, and capital expenditures. The Company's ability to meet its obligations in the normal course of business up through and beyond January 1, 2009 will be dependent on the Company securing additional external financing, increasing its customer and revenue base and controlling expenses. There is no assurance that the Company will be able to increase revenues and its customer base or secure additional extended financing under commercially reasonable terms or conditions or at all.

**2. Summary of Significant Accounting Policies**

*Principles of consolidation*

The accompanying consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany transactions and accounts have been eliminated.

*Reverse stock split*

The accompanying financial statements reflect a 1-for-16 reverse stock split of the Company's common stock, approved by the board of directors and stockholders of the Company and made effective by an amendment to the Company's certificate of incorporation on October 5, 2007. All share and per share information herein that relates to the Company's common stock has been retroactively restated to reflect the reverse stock split.



### *Use of estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### *Foreign currency translation*

The Company has foreign subsidiaries in Germany, France, and Japan whose local currencies have been determined to be the functional currency. Assets and liabilities are translated using the exchange rates in effect at the balance sheet date, while income and expenses are translated using average rates that prevailed during the period. The gains or losses that result from this process are shown as cumulative translation adjustments within accumulated other comprehensive loss.

### *Cash and cash equivalents*

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

### *Property and equipment*

Property and equipment are stated at cost less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives as follows:

Computer software and equipment .....	3-5 years
Machinery and equipment .....	3-5 years
Loaner equipment .....	3 years
Furniture and fixtures .....	7 years

Repair and maintenance costs are expensed as incurred. Leasehold improvements are amortized using the straight-line method over the lesser of the estimated useful life of the asset or the term of the lease. Depreciation expense on loaner equipment is included in cost of sales in the accompanying consolidated statements of operations.

### *Intangibles and other assets*

Intangible assets with definite lives are amortized using the straight-line method and consist mainly of patents.

During 2007, 2006, and 2005, the Company capitalized costs of approximately \$390,000, \$252,000, and \$276,000, respectively, related to patent costs. Amortization is recorded over the shorter of the patent term or the estimated economic life of the patent.

The Company follows Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, to evaluate impairment of intangible assets subject to amortization and other long-lived assets. The Company periodically evaluates whether current facts or circumstances indicate that the carrying value of such assets to be held and used may not be recoverable. If such circumstances are determined to exist, an estimate of undiscounted future cash flows produced by the long-lived asset is compared to the carrying value to determine whether impairment exists. If an asset is determined to be impaired, the loss is measured based on the fair value using quoted market prices in active markets, if available. If quoted market prices are not available, the estimate of fair value is based on various valuation techniques, including the discounted value of estimated future cash flows.

### *Research and development*

Research and development costs are expensed as incurred.

### *Concentration of credit risk and allowance for doubtful accounts*

Financial instruments that potentially subject the Company to credit risk consist principally of cash and cash equivalents and accounts receivable. The Company maintains its cash and cash equivalents with high-quality financial institutions to mitigate this credit risk. The Company performs ongoing credit evaluations of its customers and generally does not require collateral. The Company records an allowance for doubtful accounts when it becomes probable and estimable that a receivable will not be collected. Past-due status is based on contractual terms. Past-due amounts are written off against the allowance for doubtful accounts when collection is deemed unlikely and all collection efforts have ceased. One customer accounted for approximately 15% of accounts receivable at December 31, 2007 and during 2007 no one customer accounted for greater than 10% of sales. One customer accounted for approximately 13% of accounts receivable at December 31, 2006 and during 2006 no one customer accounted for greater than 10% of sales. The following table summarizes the changes in the Company's allowance for doubtful accounts for the period indicated.

	Year ended December 31,		
	2007	2006	2005
Balance at the beginning of the period . . . . .	\$ 173,070	\$ 99,640	\$100,000
Amounts to expense . . . . .	52,694	325,231	8,942
Accounts written off . . . . .	(105,764)	(251,801)	(9,302)
Balance at the end of the period . . . . .	<u>\$ 120,000</u>	<u>\$ 173,070</u>	<u>\$ 99,640</u>

### *Revenue recognition*

The Company's SurgASSIST surgical platform includes cutting and stapling devices in a variety of sizes and linear, right angle and circular configurations designed for differing surgical needs, which the Company refers to as Intelligent Surgical Instruments. The Company's Intelligent Surgical Instruments are available as disposable, single-patient devices as well as in a reusable multiple-patient format which can be autoclaved and used in multiple cases. The Company's reusable Intelligent Surgical Instruments use disposable cutting and stapling cartridges in various sizes, which the Company refers to as reload cartridges.

In the original configuration of the SurgASSIST system, Intelligent Surgical Instruments must be connected through a flexible shaft, or FlexShaft, to a power console and, in some cases, a separate remote control unit. The Company's next generation products, beginning with the i60 linear stapler that was introduced in the fourth quarter of 2007, are self-contained hand held instruments that do not require a FlexShaft or separate power console.

Most of the Company's revenue historically has been derived from the sale of single-patient, disposable Intelligent Surgical Instruments and from the sale of reload cartridges for reusable Intelligent Surgical Instruments. Revenue related to the sale of such individual products is recognized when persuasive evidence of an arrangement exists, delivery has occurred, the sale price is fixed and determinable, and collectibility is reasonable assured, which is generally at the time of shipment upon delivery to a common carrier.

The Company also derived a limited amount of revenue from the sale of complete SurgASSIST systems, consisting of one or more Intelligent Surgical Instruments, together with the related power console, FlexShaft and remote control unit. Revenue related to the complete sale of a SurgASSIST

system is recognized at the time of shipment upon delivery to a common carrier. Sales of these complete systems have not been significant during any period presented.

The Company has historically provided power consoles, FlexShafts, remote control units and mobile carts associated with its first-generation SurgASSIST system to customers at no cost as loaner equipment. In addition, the Company has in certain cases agreed to transfer title to such systems to the customer upon the customer's purchase of a specified number of disposable Intelligent Surgical Instruments although the customer is under no obligation to purchase the Intelligent Surgical Instruments. In these instances, the Company recognizes revenue attributable to the complete system as the Intelligent Surgical Instruments are delivered, in accordance with EITF 00-21, *Revenue Arrangements with Multiple Deliverables*.

In 2007, the Company instituted a program whereby it may provide reusable Intelligent Surgical Instruments and FlexShafts to customers at no cost. In certain cases, the Company offers such Intelligent Surgical Instruments and FlexShafts at no cost in exchange for higher unit pricing on the sale of reload cartridges over a specified period of time. In these cases, the Company recognizes the revenue ratably over the period of delivery of the reload cartridges in accordance with the guidance of EITF 00-21, as long as such revenue is not contingent on the delivery of the undelivered products. In addition, the Company currently makes its i60 and iDrive instruments available to customers at no cost without conditions. The Company recognizes revenue related to reload cartridges for such instruments as such reload cartridges are delivered.

The Company's customers generally order product using standard purchase orders and payment terms are 30 days. The Company provides discounted pricing to its customers based on volume and commitment levels. Allowance for product returns are estimated based on historical experience and provisions are recorded at the time of shipment. The Company also provides limited warranties to its customers against material defects in materials and workmanship. Such warranties are generally for a one year period from the date of shipment. Historically, warranty costs have not been material.

During 2007, the Company's revenues were from customers located in North America (82%) and Europe (18%). During 2006, the Company's revenues were from customers located in North America (79%) and Europe (21%). During 2005, the Company's revenues were from customers located in North America (71%) and Europe (24%) and Asia (5%). Amounts billed to customers for shipping and handling of products are included in sales. Costs incurred related to shipping and handling are included in cost of sales.

#### *Inventory*

Inventory is stated at the lower of cost or market value, with cost being determined on a first-in, first-out (FIFO) basis and market value based on the lower of replacement cost, or the estimated net realizable value, reduced by an allowance for a normal profit margin. Inventory consists of the following:

	December 31	
	2007	2006
Raw materials .....	\$3,861,162	\$2,575,848
Work in process .....	1,066,864	589,630
Finished goods .....	2,443,179	1,310,215
	<u>\$7,371,205</u>	<u>\$4,475,693</u>

During the years ended December 31, 2007, 2006, and 2005, the Company recorded inventory obsolescence charges in the amount of approximately \$506,000, \$585,000, and \$2,800,000, respectively. Such charges are reflected in cost of sales in the accompanying consolidated statements of operations.

### *Fair value of financial instruments*

The Company's financial instruments consist mainly of cash and cash equivalents, accounts receivable, accounts payable, and debt instruments. Their respective carrying amounts approximate fair value due to their short-term nature. The fair value of the debt instruments approximates their carrying amounts, as the interest rates reflect the market rates currently available to the Company.

### *Income taxes*

The provision for income taxes is determined using the asset and liability method of accounting for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred income tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted income tax rates and laws that will be in effect when the differences are expected to reverse.

### *Stock based compensation*

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004), *Share-Based Payment* (SFAS No. 123(R)), which replaces SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123), and supersedes Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25). SFAS No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values beginning with the first annual period after December 15, 2005. SFAS No. 123(R) requires that an entity measure the cost of equity-based service awards based on the grant-date fair value of the award and recognize the cost of such award over the period during which the employee is required to provide service in exchange for the award (vesting period). The pro forma disclosures previously permitted under SFAS No. 123 are no longer an alternative to financial statement recognition. The Company adopted SFAS No. 123(R) on January 1, 2006 using the prospective transition method, which required that all new stock-based awards granted subsequent to adoption be recognized in the financial statements at fair value. The Company accounts for equity issued to nonemployees in accordance with EITF 96-18, *Accounting for Equity Investments that are Issued to Other Than Employees for Acquiring, or in Conjunction with, Selling Goods or Services* (EITF 96-18).

The Company estimated the fair value of its common stock during 2006 by utilizing a retrospective, third party valuation performed by The Baker-Meekins Company, Inc. (Baker-Meekins). The Company estimated the fair value of its common stock during 2007 prior to its initial public offering in October 2007 by utilizing a contemporaneous third party valuation performed by Baker-Meekins. Subsequent to the completion of the initial public offering, the Company utilizes the quoted market price as the fair value of its common stock. The valuation methodology utilized by Baker-Meekins relied primarily on the "income approach" to estimate enterprise value. The income approach involves projecting future cash flows and discounting them to present value using a discount rate based on a risk adjusted weighted average cost of capital of comparable companies. The projection of future cash flows and the determination of an appropriate discount rate involve a significant level of judgment. In order to allocate the enterprise value to the various securities that comprise the Company's capital structure, the option-pricing method was used. The 2007 Baker-Meekins valuation yielded a fair value of \$7.68 during the second quarter of 2007 and the retrospective valuation of the Company's common stock yielded a range of fair values of \$4.48 to \$7.68 during 2006. The options granted during the second quarter of 2007 include 380,068 options granted to an executive officer which are performance based and vest only upon the achievement of certain corporate performance targets in 2007. See Note 8 for further information on the performance grant to an executive officer.

The per-share weighted average fair value on the date of grant of the options granted was estimated at \$5.42 during 2007 and \$4.16 during 2006 using the Black-Scholes option-pricing model

with the following weighted average assumptions, which are based upon Company history or industry comparative information:

	Year ended December 31,	
	2007	2006
Expected dividend yield .....	0%	0%
Expected volatility .....	58%	65%
Risk-free interest rates .....	4.40%	4.70%
Expected life .....	7 years	7 years

The expected volatility was calculated for each date of grant based on an alternative method (defined as "calculated value"). The Company identified similar public entities for which share price information is available and has considered the historical volatility of these entities' share prices in estimating expected volatility. The Company used the average volatility of these guideline companies over a seven year period, consistent with the expected term calculated pursuant to Staff Accounting Bulletin No. 107. Compensation expense under SFAS No. 123(R) and EITF 96-18 for the year ended December 31, 2007 related to share-based service awards and performance based grants granted in 2007 and 2006 was \$1,010,664, of which \$5,063 is included in cost of sales, \$92,511 is included in sales and marketing, \$28,958 is included in research and development and \$884,132 is included in general and administrative expense in the accompanying consolidated statements of operations. The Company recognizes the compensation expense of such share-based service awards on a straight-line basis. Total compensation cost of options granted but not yet vested as of December 31, 2007, exclusive of the performance grant to an executive officer in the second quarter of 2007, was \$2,384,483, net of estimated forfeitures, which is expected to be recognized over the weighted average period of 2.3 years. Compensation expense under SFAS No. 123(R) and EITF 96-18 for the year ended December 31, 2006 related to share-based service awards granted in 2006 was \$190,105, of which \$1,193 is included in cost of sales, \$40,923 is included in sales and marketing and \$147,989 is included in general and administrative expense in the accompanying consolidated statements of operations. The Company utilized an estimated forfeiture rate of 15% for their 2006 and 2007 grants, based on the Company's historical forfeiture rate as well as an analysis of current market conditions.

Prior to 2006, the Company accounted for its stock-based compensation plans in accordance with APB 25 and the related interpretations. Under APB 25, no compensation expense is recognized if the exercise price of the Company's stock options equals or exceeds the fair value of the underlying common stock at the date of grant. As the Company had used the minimum value method for valuing its stock options under the disclosure requirements of SFAS 123, all options granted prior to January 1, 2006 continue to be accounted for under APB 25. Additionally, the pro forma disclosures that were required under the original provisions of SFAS No. 123 are no longer required for outstanding awards accounted for under the intrinsic-value method of APB 25 in periods after adoption of SFAS No. 123(R).

#### *Recent accounting pronouncement*

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. The Company adopted FIN 48 on January 1, 2007. The adoption did not have a material impact on its consolidated financial statements.

### *Redeemable convertible preferred stock*

The Company accounts for stock subject to provisions for redemption that are outside of its control as mezzanine equity. These securities are recorded at fair value at the date of issue and are accreted to the minimum redemption amount at each balance sheet date. The resulting increases in the carrying amount of the redeemable stock are reflected through decreases in additional paid-in capital.

The Company accounts for redeemable convertible preferred stock and the related common stock warrants in accordance with the provisions of SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* SFAS 133, and EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (EITF 00-19)*. Pursuant to this guidance, the Company has concluded that the conversion and redemption features of the redeemable convertible preferred stock are not embedded derivatives that need to be bifurcated from the host instrument and separately valued. In addition, the Company has accounted for its detachable common stock warrants as a component of stockholder's equity in accordance with the guidance of EITF 00-19.

### *Net loss attributable to common shares*

The Company computes net loss per share in accordance with SFAS No. 128, *Earnings Per Share* (SFAS No. 128). Under SFAS No. 128, basic net loss per share is computed by dividing net loss per share available to common stockholders by the weighted average number of common shares outstanding for the period and excludes the effects of any potentially dilutive securities. Diluted earnings per share, if presented, would include the dilution that would occur upon the exercise or conversion of all potentially dilutive securities into common stock using the "treasury stock" and/or "if converted" methods as applicable.

The following summarizes the potential outstanding common stock of the Company as of the end of each period:

	<u>December 31, 2007</u>	<u>December 31, 2006</u>	<u>December 31, 2005</u>
Redeemable convertible preferred stock	—	8,873,412	5,711,396
Convertible senior secured promissory notes	2,643,175	—	—
Common stock warrants	1,137,864	1,150,549	710,242
Common stock options outstanding	1,728,844	1,216,729	1,142,267
Common stock options available for grant	643,510	257,093	185,001
Total	<u>6,153,393</u>	<u>11,497,783</u>	<u>7,748,906</u>

If the outstanding options, warrants, and preferred stock were exercised or converted into common stock, the result would be anti-dilutive, due to the company's loss position in all periods presented. Accordingly, basic and diluted net loss attributable to common stockholders per share are identical for all periods presented in the accompanying consolidated statements of operations.

### *Segment information*

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, establishes standards for reporting information regarding operating segments in annual financial statements and requires selected information of those segments to be presented in interim financial reports issued to stockholders. Operating segments are identified as components of an enterprise about which separate financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company views its operations and manages its business as one operating segment.

The Company's German operations accounted for approximately 15% of consolidated sales in 2007 and 18% in both 2006 and 2005, respectively. The Company's French operations accounted for approximately 3% of sales in 2007 and 2006 and 0.3% of consolidated sales in 2005. The Company's Japan operations accounted for approximately 0.2% of sales in 2007. There were minimal sales in 2006 and no Japanese sales in 2005. In addition, approximately 4% and 5% of the Company's consolidated assets are located in Germany at December 31, 2007 and 2006, and approximately 0.8% and 0.1% of the Company's consolidated assets are located in France at December 31, 2007 and 2006, respectively. Japanese operations commenced in December 2006 and approximately 0.7% of the Company's consolidated assets are located in Japan.

### 3. Property and Equipment

Property and equipment consist of the following:

	December 31	
	2007	2006
Machinery and equipment . . . . .	\$ 5,376,517	\$ 4,344,844
Loaner equipment . . . . .	856,134	632,110
Leasehold improvements . . . . .	2,471,949	2,202,394
Computer equipment and software . . . . .	1,693,886	1,341,356
Furniture and fixtures . . . . .	894,188	770,734
Office equipment . . . . .	185,734	168,906
	<u>11,478,408</u>	<u>9,460,344</u>
Less accumulated depreciation . . . . .	<u>(6,765,398)</u>	<u>(4,588,894)</u>
	<u>\$ 4,713,010</u>	<u>\$ 4,871,450</u>

During the years ended December 31, 2007, 2006, and 2005 the Company recognized approximately \$2,185,000, \$1,971,000 and \$1,389,000 respectively, of depreciation expense in the accompanying consolidated statements of operations.

### 4. Accrued Expenses

Accrued expenses consist of the following:

	December 31	
	2007	2006
Accrued interest . . . . .	\$1,463,194	\$ —
Accrued purchases . . . . .	1,271,125	605,252
Accrued compensation . . . . .	801,377	423,444
Accrued professional fees . . . . .	496,159	330,512
Legal reserve . . . . .	100,000	285,000
Deferred rent . . . . .	187,711	149,003
Other . . . . .	187,182	379,248
	<u>\$4,506,748</u>	<u>\$2,172,459</u>

### 5. Letter of Credit and Restricted Cash

During 2004, the Company entered into a new lease agreement for its headquarters and principal operating facility, which commenced January 1, 2005. Per the terms of the agreement, the Company was required to furnish a letter of credit in the amount of \$1,020,000. The Company pledged \$1,020,000 of cash as collateral for the letter of credit. The letter of credit and the amount of restricted

cash will be reduced annually under the provisions of the lease. During 2006, the letter of credit and related cash collateral was reduced to \$879,310. During the first quarter of 2007, the letter of credit and cash collateral further reduced to \$738,621. During March 2007, the Company sold \$25.0 million of convertible senior secured promissory notes which generated net proceeds to the Company of \$23,298,654 (\$25,000,000 less financing fees of \$1,701,346). Of this amount, \$3,500,000 was placed in escrow to fund the first four interest payments on the convertible notes (Note 12). A total of \$875,000 of such escrowed amount was utilized for the first interest payment on the convertible notes during 2007. In December 2007, the Company provided a bank guarantee of €500,000 (\$736,450 at December 31, 2007) as a condition of obtaining a stay of the provisional enforcement of a patent infringement decision. The above amounts are included as restricted cash on the accompanying consolidated balance sheets.

## **6. Redeemable Convertible Preferred Stock**

### *Series A Redeemable Convertible Preferred Stock*

During August 2003, the Company commenced a private placement offering of a Series A Convertible Preferred Stock (Series A). Through December 2003, the Company sold 9,189,073 shares of Series A at \$0.6992 per share, generating net proceeds of \$6,061,943 (\$6,425,000 less offering costs of \$363,057). During 2004, the Company sold an additional 13,479,691 shares of Series A for \$0.6992 per share, generating net proceeds of \$9,363,787 (\$9,425,000 less offering costs of \$61,213). In connection with the 2004 offering, each purchaser of a share of the Series A also received a ten-year warrant to acquire at \$11.19 per share additional shares of common stock at ratios ranging from 1:60 to 1:100 (the Series A Warrants). A total of 208,050 Series A Warrants were issued. The fair value of the Series A Warrants was estimated using the Black Scholes method, with the following assumptions: expected dividend yield: 0%, expected volatility: 65%, risk free interest rate: 4.5%, expected life: 5 years. The calculation resulted in a grant date fair value of \$1.60 per warrant. The total fair value of \$332,880 was allocated to additional paid-in capital upon the issuance of the Series A Warrants. As of December 31, 2007 149,772, of these warrants remain outstanding. The exercise price is subject to adjustment under certain circumstances as described in the Series A Warrants.

Each share of Series A was convertible at any time into a number of shares of the Company's common stock determined by dividing the original purchase price by the applicable conversion price, as defined. Series A shares were convertible on a one-for-one (i.e., one share of Series A preferred stock for one share of common stock) basis at December 31, 2006. The Series A would automatically convert into shares of common stock immediately upon the closing of a firm commitment underwritten public offering of shares of common stock of not less than \$40 million (prior to underwriting commissions and discounts) at a price to the public of at least \$13.28 per share (adjusted for stock splits subsequent to the Company's reverse stock split in October 2007, stock dividends or recapitalizations) (a Qualified IPO), or the date upon which the holders of a majority of the Company's outstanding preferred stock (a Preferred Majority) have consented to such conversion.

By a written consent effective as of September 21, 2007, the holders of a Preferred Majority agreed that all outstanding shares of each series of the Company's preferred stock would be converted to common stock immediately prior to the Company's initial public offering. This consent was subject to the conditions that the value of the Company's common stock outstanding prior to the offering, determined on a fully diluted basis in a manner specified in the consent, and valued at the initial public offering price, was at least \$125 million in the aggregate, and that the offering occurred before January 31, 2008.

The Series A was entitled to the number of votes equal to the number of shares of common stock into which the Series A would convert. Such conversion rate was subject to adjustment as defined in the Company's Certificate of Incorporation. The conversion rate was subject to anti-dilution



adjustments, whereby if the Company issues or sells certain securities (Additional Shares) for a value less than the conversion price in effect immediately prior to such issuance, the conversion price would be reduced to a price equal to the current conversion price multiplied by a fraction, the numerator of which is equal to the number of shares of common stock outstanding immediately prior to the equity issuance plus the number of shares of common stock that the aggregate consideration received by the Company for the total number of Additional Shares of common stock so issued would purchase at the conversion price in effect immediately prior to such Additional Share issuance, and the denominator of which is equal to the number of shares of common stock outstanding immediately prior to the Additional Share issuance plus the number of Additional Shares issued. The conversion price would also be adjusted in the event of a stock dividend, stock split or similar event. These adjustments are referred to as "Preferred Stock Conversion Adjustments".

The Series A had a liquidation preference equal to the original purchase price plus any accrued but unpaid dividends. Dividends accrued cumulatively at the rate of 6% per year and was payable if and when declared by the Company's board of directors. The Series A was redeemable at the original purchase price plus accrued and unpaid dividends at the option of the holders anytime after May 30, 2011 (the Redemption Date). The carrying amount of the Series A was being accreted to the redemption amount using the effective interest method through charges to additional paid in capital. Accrued and unpaid dividends were \$3,641,606 and \$2,850,087 at October 31, 2007 and December 31, 2006 respectively. If the Company was unable to redeem the Series A, the Series A would begin accruing cumulative dividends at the rate of 8% until redeemed in full. All Series A preferred stock and accrued dividends thereon converted to common stock on October 31, 2007 in connection with the Company's initial public offering.

#### *Series B Redeemable Convertible Preferred Stock*

During September 2004, investors agreed to purchase 47,489,822 shares of the Company's Series B Convertible Preferred Stock (Series B), which generated net proceeds to the Company of \$34,809,675 (\$35,000,000 less offering costs of \$190,325).

The Series B had a liquidation preference equal to the original purchase price plus any accrued but unpaid dividends. The Series B accrued dividends cumulatively at the rate of 10% per annum and such dividends were payable when declared by the board of directors. Each share of Series B was convertible at any time into the Company's common stock on a one-for-one basis, subject to Preferred Stock Conversion Adjustments, at December 31, 2006. The Series B would automatically convert into shares of common stock immediately upon the closing of a Qualified IPO, or the date upon which a Preferred Majority has consented to such conversion. The Series B was redeemable, at its original purchase price plus the accrued and unpaid dividends, at the option of the Series B holder at any time after the Redemption Date. The carrying amount of the Series B was being accreted to the redemption amount using the effective interest method through charges to additional paid in capital. Accrued and unpaid dividends were \$10,937,500 and \$8,020,832 at October 31, 2007 and December 31, 2006, respectively. If the Company was unable to redeem the Series B, the dividends would begin accruing at the rate of 12% until redeemed in full. All Series B preferred stock and accrued dividends thereon converted to common stock on October 31, 2007 in connection with the Company's initial public offering.

In connection with this financing, one of the investors was granted exclusive rights to distribute the Company's products in Japan. Sales under the distribution agreement were \$83,066, \$18,284, and \$589,566 for the years ended December 31, 2007, 2006 and 2005 respectively.

### *Series C Redeemable Convertible Preferred Stock*

During October 2005, investors agreed to purchase 21,223,750 shares of the Company's Series C Convertible Preferred Stock (Series C), which generated net proceeds to the Company of \$16,534,482 (\$16,656,408 less offering costs of \$121,926).

The Series C had a liquidation preference equal to the original purchase price plus any accrued but unpaid dividends. The Series C accrued dividends cumulatively at the rate of 6% per annum and such dividends were payable when declared by the Board of Directors. Each share of Series C was convertible into the Company's Common Stock on a sixteen-for-one basis, subject to Preferred Stock Conversion Adjustments. The Series C would automatically convert into shares of Common Stock immediately upon the closing of a Qualified IPO, or the date upon which a Preferred Majority has consented to such conversion. The Series C was redeemable, at its original purchase price plus the accrued and unpaid dividends, at the option of the Series C holder at any time after the Redemption Date. The carrying amount of the Series C was being accreted to the redemption amount using the effective interest method through charges to additional paid in capital. Accrued and unpaid dividends were \$2,062,970 and \$1,229,938 at October 31, 2007 and December 31, 2006 respectively. If the Company was unable to redeem the Series C, the dividends would begin accruing at the rate of 8% until redeemed in full. All Series C preferred stock and accrued dividends thereon converted to common stock on October 31, 2007 in connection with the Company's initial public offering.

### *Series D Redeemable Convertible Preferred Stock*

During 2006, investors agreed to purchase 50,596,158 shares of the Company's Series D Convertible Preferred Stock (Series D), which generated net proceeds to the company, including the conversion of an outstanding bridge loan, of \$37,236,510 (\$40,982,888 less offering costs of \$3,746,378).

Upon any liquidation or change of control, the holders of Series D Preferred would receive, in preference to holders of the Series A, B, and C Convertible Preferred Stock, common stock, or other securities, an amount equal to 100% of the Series D original purchase price plus any accrued but unpaid dividends. The Series D accrued dividends cumulatively at the rate of 6% per annum and such dividends were payable when declared by the board of directors. Each share of Series D was convertible into the Company's common stock on a one-for-one basis, subject to Preferred Stock Conversion Adjustments, at December 31, 2006. The Series D would automatically convert into shares of common stock immediately upon the closing of a Qualified IPO, or the date upon which a Preferred Majority has consented to such conversion. The Series D was redeemable at its original purchase price plus the accrued and unpaid dividends, at the option of the Series D holder at any time after the Redemption Date. The carrying amount of the Series D was being accreted to the redemption amount using the effective interest method through charges to additional paid in capital. Accrued and unpaid dividends were \$3,186,201 and \$1,137,056 at October 31, 2007 and December 31, 2006, respectively. If the Company was unable to redeem the Series D, the dividends would begin accruing at the rate of 8% until redeemed in full. All Series D preferred stock and accrued dividends thereon converted to common stock on October 31, 2007 in connection with the Company's initial public offering.

In connection with the Series D offering, certain investors and the placement agent were issued an aggregate of 431,502 five-year warrants to acquire additional shares of Common Stock at \$12.60 per share (the Series D Warrants). The fair value of the Series D Warrants was estimated using the Black Scholes method with the following assumptions: expected dividend yield: 0%, expected volatility: 65%, risk free interest rate: 4.5%, expected life: 5 years. The calculation resulted in a grant date fair value of \$3.52 per warrant. The total fair value of \$1,477,168 was allocated to additional paid-in capital upon the issuance of the Series D Warrants.

Prior to the initial closing of this financing, the Company borrowed \$6,000,000 from a trust affiliated with a director. This bridge loan accrued interest at the rate of 8% per annum and also

entitled the lender to the receipt of 24,494 common stock warrants, with an exercise price of \$12.25 per share (the Bridge Warrants). The fair value of the Bridge Warrants as calculated via the Black Scholes model and the related beneficial conversion feature of approximately \$171,000 was allocated to debt discount. At the initial closing of Series D, the principal amount of the bridge loan and accrued interest of \$70,795 were converted into 7,494,800 shares of Series D at \$0.81 per share and the remaining debt discount on the bridge loan was recognized as interest expense.

At December 31, 2007, the Company had 5,000,000 shares of undesignated preferred stock authorized. No preferred shares are issued or outstanding, as of December 31, 2007.

## **7. Common Stock**

During 2005, the Company's board of directors and stockholders amended its Certificate of Incorporation increasing the authorized shares of common stock to 192,935,780 and the authorized shares of Series A, Series B, and Series C to 93,094,368. During 2006, the Company's board of directors and stockholders further amended its Certificate of Incorporation increasing the authorized shares of common stock to 260,000,000 and the authorized shares of Series A, Series B, Series C, and Series D to 144,049,147. During March 2007, the Company's board of directors and stockholders further amended its Certificate of Incorporation to increase the authorized shares of common stock to 316,000,000. During October 2007, the Company's board of directors and stockholders further amended its Certificate of Incorporation to decrease the authorized shares of common stock to 200,000,000. The Company's common stock is junior in right of liquidation to the Company's preferred stock. Each share of common stock has one vote for the election of directors and other matters as described in the bylaws. Holders of common stock are entitled to receive, when and if declared by the Company's board of directors, dividends subject to the preferential rights of the preferred stock shareholders.

During May 2005, the Company offered to holders of certain outstanding common stock purchase warrants the option to exercise such warrants at an exercise price of \$11.79 per share which was equal (on split-affected basis) to the price per share of the Series B sold in September 2004. Certain warrant holders exercised a total of 278,515 of such warrants generating proceeds of \$3,284,251. This offer expired on June 3, 2005, and any warrants not exercised on or before such date continue to be governed by all of the terms set forth in the original warrant agreement including the stated exercise price. Due to the short period of time during which such offer was available and the lack of an intrinsic value attributable to such warrants, the impact of this offer on net loss applicable to common shares was de minimis.

## **Warrants**

The Company issued warrants to preferred shareholders, lenders, and a licensor. Certain warrants were adjusted to reflect anti-dilution provisions included in the original warrant agreements.

The following table summarizes the warrants outstanding and exercisable as of December 31, 2007:

<u>Number of Shares of Common Stock Issuable Upon Exercise of Outstanding Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
12,608 .....	\$11.30 .....	October 2009
420,757 .....	\$13.29 .....	Various
4,688 .....	\$12.96 .....	October 2011
73,951 .....	\$12.16 .....	April 2008
52,324 .....	\$11.04 .....	January 2014
6,795 .....	\$11.04 .....	March 2014
90,603 .....	\$11.04 .....	April 2014
20,142 .....	\$11.79 .....	May 2015
24,494 .....	\$12.25 .....	June 2011
151,869 .....	\$12.60 .....	June 2011
279,633 .....	\$12.60 .....	August 2011
<u>1,137,864</u>		

The following table summarizes the warrants outstanding and exercisable as of December 31, 2006:

<u>Number of Shares of Common Stock Issuable Upon Exercise of Outstanding Warrants</u>	<u>Exercise Price</u>	<u>Expiration Date</u>
12,259 .....	\$11.62 .....	October 2009
452,338 .....	\$13.73 .....	Various
4,687 .....	\$12.96 .....	October 2011
69,872 .....	\$12.87 .....	April 2008
51,621 .....	\$11.19 .....	January 2014
6,704 .....	\$11.19 .....	March 2014
89,387 .....	\$11.19 .....	April 2014
20,141 .....	\$11.79 .....	May 2015
23,891 .....	\$12.56 .....	June 2011
147,697 .....	\$12.96 .....	June 2011
271,952 .....	\$12.96 .....	August 2011
<u>1,150,549</u>		

In March 2007, the Company extended the expiration date of 452,338 warrants with a strike price of \$13.73 held by a shareholder and director which were scheduled to expire in May 2007. In exchange for the amendment and extension of these warrants, the holder agreed to purchase a minimum of \$1 million of the convertible senior secured promissory notes due March 2010 (see Note 12). The expiration dates of the warrants were extended such that 10% of the warrants shall expire on May 22, 2007 and 22.5% shall expire annually on May 22, 2008 through May 22, 2011. The fair value of the warrants was estimated using the Black Scholes fair value pricing model with the following assumptions: expected dividend yield: 0%, expected volatility: 60%, risk free interest rate: 4.58%, and expected lives ranging from 1.23 to 4.23 years based on the remaining contractual life of each individual warrant tranche. The fair value of the Company's common stock was estimated at \$7.68 per share as determined by the contemporaneous third party valuation provided by Baker-Meekins. The calculation resulted in grant date fair values of \$0.79, \$1.56, \$2.21 and \$2.77 for the warrants expiring in 2008, 2009, 2010 and 2011, respectively. The total fair value of \$747,000 was allocated to debt discount and will be amortized to interest expense over the term of the convertible senior secured promissory notes.

In May 2007, 45,233 warrants held by a shareholder and director were exercised for total proceeds of \$621,115. The exercise price of all of the outstanding warrants as of December 31, 2007 was lower than the quoted market price of the Company's common stock and therefore, the warrants have intrinsic value totaling \$1,347,710 at December 31, 2007. All outstanding warrants are subject to anti-dilution adjustments, whereby if the Company issues or sells certain securities (Additional Shares) for a value less than the exercise price of the warrant, the exercise price of the warrant would be reduced to a price equal to the exercise price of the warrant multiplied by a fraction, the numerator of which is equal to the number of shares outstanding immediately prior to the equity issuance plus the number of shares of common stock that the aggregate consideration received by the Company for the total number of Additional Shares of common stock so issued would purchase at the warrant exercise price in effect immediately prior to such Additional Share issuance, and the denominator of which is equal to the number of shares of common stock outstanding immediately prior to the Additional Share issuance plus the number of Additional Shares issued. The warrants also provide that upon an adjustment of the exercise price of the warrant, the number of shares issuable under the warrant shall be increased by that number of shares determined by multiplying the exercise price in effect immediately prior to such adjustment by the number of shares issuable under the warrant immediately prior to such adjustment and dividing the product thereof by the new exercise price of the warrant.

## **8. Stock Option Plan**

The Company adopted 1999 and 2000 Stock Option Plans (the 1999 Plan and 2000 Plan, respectively). The 1999 Plan and the 2000 Plan provide for stock options to be granted as incentive stock options as well as stock options that do not qualify as incentive options and restricted stock awards. A maximum of 760,367 shares of Common Stock were available for grant under the 1999 Plan and the 2000 Plan. All directors, officers, key employees and consultants of the Company are eligible to receive options under the 1999 Plan and the 2000 Plan.

During September 2004, the Company's board of directors adopted the 2004 Stock Incentive Plan (the 2004 Plan) authorizing an aggregate of 234,356 shares of Common Stock to be issued upon exercise of options and restricted stock awards granted under the 2004 Plan. During November 2005, the Company's board of directors authorized an increase in the number of shares that may be issued under the 2004 Plan to 604,992. During October 2006, the Company's board of directors authorized an increase in the number of shares that may be issued under the 2004 Plan to 758,142. During January 2007, the Company's board of directors amended the Company's 2004 Stock Incentive Plan to increase the total number of shares of common stock reserved for issuance under the Plan to 1,659,966. Total shares reserved for issuance under all stock option plans is 2,434,985.

In April 2007, the Company's board of directors adopted and the stockholders approved the 2007 Employee Stock Purchase Plan and the 2007 Equity Incentive Plan (2007 Plan). Options and restricted stock awards may be granted to employees, officers or directors of, or consultants or advisors to, the Company provided that incentive stock options may be granted only to employees. The option price for incentive options issued under the 2004 Plan must be at least equal to 100% of the fair market value of the common stock or less than 110% of such fair market value if granted to a greater than 10% shareholder as of the date the option is granted if the option is intended to qualify as an incentive stock option. As of December 31, 2007, no incentive options have been granted by the Company. Generally, options granted under the 2004 Plan and the 2007 Plan vest over four years from the date of grant and expire ten years after the date granted. Options also terminate (i) three months after the date on which employment is terminated (whether such termination is voluntary or involuntary), other than by reason of death or disability; and (ii) one year from the date of termination due to death or disability, but in any event not later than the scheduled termination date.

The following table summarizes stock option activity under the 1999 Plan, 2000 Plan 2004 Plan and 2007 Plan:

	Number of Shares	Weighted Average Exercise Price
Outstanding, December 31, 2003	662,018	\$5.92
Options granted	282,857	4.64
Options cancelled/forfeited	(179,639)	5.76
Options exercised	(18,360)	4.48
Outstanding, December 31, 2004	746,876	5.92
Options granted	540,848	6.40
Options cancelled/forfeited	(124,515)	5.60
Options exercised	(20,942)	8.80
Outstanding, December 31, 2005	1,142,267	5.92
Options granted	440,094	9.44
Options cancelled/forfeited	(364,661)	5.92
Options exercised	(971)	4.80
Outstanding, December 31, 2006	1,216,729	7.20
Options granted	871,481	11.28
Options cancelled/forfeited	(356,145)	9.90
Options exercised	(3,221)	6.01
Outstanding, December 31, 2007	1,728,844	8.69
Exercisable, December 31, 2007	881,977	6.80

During January 2006 the Company granted a restricted stock award of 5,000 shares of common stock to a consultant at a price of \$0.16 per share. The shares vested during 2006. In connection with this award, the Company recognized \$21,600 in general and administrative expense during 2006 for the estimated fair value of the award less the cash consideration paid by the consultant.

During January 2007, the Company granted restricted stock awards of 172 shares of common stock to certain employees. The shares immediately vested. In connection with these awards, the Company recognized \$1,265 in sales and marketing expense for the estimated fair value of the awards.

In April 2007, the board of directors granted an executive officer a non-statutory option to purchase 380,068 shares of common stock at an exercise price of \$10.24 per share, in connection with the execution of his employment agreement. This option is performance-based and will vest only upon the achievement of corporate performance targets beginning in 2007. Specifically, 25% of the shares will vest upon the completion of a qualified initial public offering, 25% will vest upon the successful launch of a specified new product (as defined in the employment agreement), up to 40% will vest upon achievement of a revenue target for 2007, and up to 10% will vest upon achievement of a gross margin target for 2007. Additionally, all of the shares would vest upon a change in control of the Company, as defined in the employment agreement. The Company estimated the fair value of the options using the Black Scholes fair value pricing model with the following assumptions: expected dividend yield: 0%, expected volatility: 60%, risk free interest rate: 4.58%, and expected life of 7 years. The fair value of the Company's Common Stock was estimated at \$7.68 per share as determined by the contemporaneous third party valuation provided by Baker-Meekins. The expected volatility was calculated for the grant based on an alternative method (calculated value), using the approach disclosed in Note 2. The calculation yielded a grant date fair value of \$4.48 for the options, or a total fair value of approximately \$1.69 million. In the fourth quarter of 2007, the Company recognized \$423,547 of compensation expense in general and administrative expense as the target related to the successful

launch of a new product was achieved. The remaining targets were not achieved, and therefore, the remaining 285,051 options are not expected to vest.

Of the 871,481, 440,094 and 540,848 stock options granted in 2007, 2006, and 2005, respectively, 23,125, 8,000 and 6,875 options were issued to nonemployees for services rendered and to be rendered. These options were valued using a fair value pricing model and the resulting compensation expense was not material.

The following table summarizes information about stock options outstanding at December 31, 2007: .

Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life
\$ 4.48 . . . . .	359,468	6.0
6.40 . . . . .	335,985	7.4
7.04 . . . . .	83,597	5.2
8.00 . . . . .	15,625	2.8
10.24 . . . . .	680,797	8.5
12.80 . . . . .	26,409	4.3
14.25 . . . . .	226,963	9.9
	<u>1,728,844</u>	

The following table summarizes information about stock options outstanding at December 31, 2006:

Exercise Price	Options Outstanding	Weighted Average Remaining Contractual Life
\$ 4.48 . . . . .	362,300	6.9
6.40 . . . . .	366,306	7.8
7.04 . . . . .	83,750	6.3
8.00 . . . . .	15,625	3.8
10.24 . . . . .	362,341	9.6
12.80 . . . . .	26,407	5.3
	<u>1,216,729</u>	

At December 31, 2007, the aggregate intrinsic value of options outstanding and vested options are \$8.9 million and \$6.2 million respectively.

## 9. Shares Reserved for Future Issuance

The Company has reserved the following shares of common stock for future issuance:

	December 31, 2007	December 31, 2006
Common stock options outstanding	1,728,844	1,216,729
Common stock options available to grant	643,510	257,093
Common stock warrants	1,137,863	1,150,549
Convertible senior secured promissory notes	3,500,000	—
Series A Convertible Preferred Stock	—	1,416,797
Series B Convertible Preferred Stock	—	2,968,113
Series C Convertible Preferred Stock	—	1,326,484
Series D Convertible Preferred Stock	—	3,162,259
	<u>7,010,217</u>	<u>11,498,024</u>

## 10. Income Taxes

Net loss before income taxes consists of the following components:

	December 31,		
	2007	2006	2005
Domestic	\$(31,343,880)	\$(24,215,426)	\$(24,465,320)
Foreign	(5,500,979)	(4,115,013)	(2,970,775)
Total	<u>\$(36,844,859)</u>	<u>\$(28,330,439)</u>	<u>\$(27,436,095)</u>

The significant components of the Company's deferred tax assets and liabilities are as follows:

	December 31,	
	2007	2006
Deferred tax assets:		
Net operating loss carryforwards	\$ 58,969,209	\$ 44,984,201
Research and development credit carryforwards	1,372,597	1,330,634
Capitalized research and development	4,174,277	4,969,946
Inventory reserve	181,854	314,805
Allowance for doubtful accounts	43,926	21,963
Property, plant and equipment	409,067	3,032
Other, net	345,506	516,820
Total deferred tax assets	65,496,436	52,141,401
Less valuation allowance	(65,496,436)	(52,141,401)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

The Company has reported a net loss since inception. This loss has not resulted in a reported tax benefit because of an increase in the valuation allowance for deferred tax assets that results from the inability to determine the realizability of those assets.



Reconciliations between expected income taxes computed at the federal rate of 34% for the years ended December 31, 2007, 2006 and 2005, respectively, and the provision for income taxes are as follows:

	Years ended December 31,		
	2007	2006	2005
Income tax benefit at statutory rate .....	(12,527,252)	\$ (9,632,349)	\$ (9,328,272)
State income tax, net of federal benefit .....	(806,030)	(610,660)	(628,559)
Nondeductible expenses .....	90,869	34,588	39,891
Research tax credit .....	(121,286)	(164,836)	(177,603)
Other .....	8,664	(13,007)	8,894
Increase in valuation allowance .....	13,355,035	10,386,264	10,085,649
Income tax provision .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

At December 31, 2007 and 2006, the Company had federal net operating loss carryforwards of approximately \$143,000,000 and \$110,000,000, respectively, to offset future federal taxable income expiring in various years through 2026. At December 31, 2007 and 2006, the Company has German net operating loss carryforwards of approximately \$12,100,000 and \$8,900,000, respectively that have no expiration period.

At December 31, 2007 and 2006, the Company has state net operating losses of \$85,000,000 and \$52,000,000 respectively that expire in various years starting in 2007.

The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences are deductible. The timing and manner in which the Company can utilize its net operating loss carryforward and future income tax deductions in any year may be limited by provisions of the Internal Revenue Code regarding the change in ownership of corporations. Such limitation may have an impact on the ultimate realization of the Company's carry forwards and future tax deductions.

## 11. Commitments and Contingencies

The Company leases certain facilities and office equipment under operating lease agreements that expire on various dates through 2012, generally with options to renew and escalating rent payments. Payments made under operating leases are charged to operations on a straight-line basis over the period of the lease. Rent expense was approximately \$780,000, \$688,000, and \$873,000 respectively, for the years ended December 31, 2007, 2006 and 2005. The Company was the lessee of approximately \$99,000 of purchased software under a capital lease which expired in 2006. The purchased software was capitalized at the present value of minimum lease payments and was amortized over its estimated productive life. The Company recognized approximately \$12,000, and \$33,000 of amortization expense in 2006 and 2005 related to this software.

Future minimum lease payments subsequent to December 31, 2007 under noncancelable operating leases are as follows:

	Minimum Payments
2008 .....	720,519
2009 .....	719,036
2010 .....	726,459
2011 .....	718,414
2012 .....	175,492
Total minimum lease payments .....	<u>\$3,059,920</u>

The Company has, on occasion, been named as a defendant in lawsuits alleging product failure, patent infringement, and breach of contract. These cases are routinely handled by external counsel. Based on the advice of counsel, management has provided reserves for the estimated potential losses, when such losses are deemed probable and estimable. The Company currently has a patent infringement case outstanding. The Company received a favorable ruling from the German courts on two of the patent infringement claims and an unfavorable ruling on one of the claims. However, the Company is in the process of appealing the ruling. The Company intends to defend this claim vigorously and has concluded it is too early to determine whether or not the Company will incur any loss under this claim. As such, no amounts are accrued in the accompanying consolidated balance sheets related to this claim.

The Company also has a product liability case outstanding which is currently suspended and the Company has continued to contest the claim. The Company has accrued \$100,000 related to this matter which represents their best estimate of the potential liability related to this claim.

## 12. Long-Term Debt

Details of long-term debt are as follows:

	December 30,	
	2007	2006
Secured loans .....	\$24,742,891	\$452,436
Less: current maturities .....	69,230	75,610
	<u>\$24,673,661</u>	<u>\$376,826</u>

Required principal payments as of December 31, 2007 for the next five years and thereafter are as follows:

Year ended December 31,	
2008 .....	69,230
2009 .....	71,158
2010 .....	25,073,140
2011 .....	75,176
2012 .....	77,270
Thereafter .....	6,535
	<u>\$25,372,509</u>

During May 2002, the Company obtained a \$15,000,000 revolving line of credit facility that expired in May 2005. At the Company's option, the outstanding borrowings were subject to either the lender's

floating base interest rate or a fixed rate per annum of LIBOR plus 200 basis points. The Company incurred approximately \$197,700 and \$524,400 of interest expense in connection with this facility during the year ended December 31, 2005 and 2004, respectively. In consideration for the credit facility, the lender was given a security interest in the Company's tangible property. The line of credit was also secured and guaranteed by an individual who is a shareholder and director of the Company. In connection with this guarantee, the Company issued the guarantor 234,375 common stock warrants at an exercise price of \$32.00 per share, expiring in May 2007, and a security interest in the intellectual property of the Company. The Company also issued the lender 2,343 common stock warrants at an exercise price of \$32.00 expiring in May 2007. The warrants issued to the guarantor have subsequently been adjusted pursuant to the anti-dilution provisions of the pre-existing warrant and, as of December 31, 2006, the warrant was exercisable for an aggregate of 452,338 shares of Common Stock at an exercise price of \$13.73 per share. The warrants held by the lender were terminated when the Company refinanced this line of credit in May 2005.

During May 2005, the Company refinanced its existing debt with a new \$10,000,000 loan. The term of the loan was 36 months with six payments of interest only, followed by 30 payments of both principal and interest. The loan was subject to an interest rate of 10.71% and was secured by the Company's tangible and intellectual property. In connection with this financing, the Company issued the lender warrants to purchase 38,161 shares of common stock at an exercise price of \$11.79 per share. The warrants were valued using the Black Scholes fair value pricing model. The resulting debt discount of \$73,000 was being amortized into interest expense over the term of the debt. In connection with this agreement, the Company capitalized approximately \$50,000 of deferred financing fees. These fees were also being amortized into interest expense over the life of the arrangement.

During December 2006, the Company paid off the 2005 loan in its entirety and 18,019 of the warrants originally issued to the lender were cancelled in connection with the repayment. The remaining debt discount and deferred financing fees, as well as a prepayment penalty of \$50,000, were charged to interest expense in December 2006 in connection with the repayment.

During March 2007, the Company sold \$25.0 million of convertible senior secured promissory notes due March 2010 (the "Convertible Notes") which generated net proceeds to the Company of \$23,298,654 (\$25,000,000 less financing fees of \$1,701,346). Of this amount, \$3,500,000 was placed in escrow to fund the first four interest payments on the Convertible Notes. These notes are secured by substantially all of the Company's assets and accrue interest initially at the rate of 7% per annum, payable semiannually in arrears, and were subject to an increase to 8.5% per annum in the event that a qualified initial public offering (a "Convertible Note Qualified IPO") did not occur by December 31, 2007. A Convertible Note Qualified IPO is defined as an underwritten public offering of common stock that results in the common stock being listed on a U.S. national securities exchange and for which the aggregate gross proceeds to the Company are not less than \$40 million (prior to underwriting commissions and discounts). The contingent adjustable interest feature in the Convertible Notes is a derivative requiring bifurcation under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*. The value of the derivative was not deemed material during 2007 and the Company completed its initial public offering in October 2007 which met the requirements of a Convertible Note Qualified IPO. Interest accruing on or before March 31, 2009 is payable in cash, while interest accruing after March 31, 2009 is payable, at the Company's option, in cash or paid-in-kind in the form of additional notes ("PIK Notes"). The principal amounts of such PIK Notes will have the same maturity as the Convertible Notes. Should the Company elect to pay interest on the Convertible Notes in PIK Notes, the interest rate on such PIK Notes shall be equal to the then applicable interest rate plus 1.5%.

The Convertible Notes also require the payment of a terminal value that (i) will be due upon redemption or conversion of the Convertible Notes, (ii) will be considered part of the conversion amount for purposes of determining the conversion rate (see below) or (iii) will be due upon maturity as part of the principal amount. In each case, the terminal value payment which, as amended, is

defined to equal 7% per annum of the applicable principal from the closing date of the Convertible Notes in March 2007 to the first Conversion Event (which the parties acknowledged and agreed occurred on October 31, 2007, the date of the Company's initial public offering), or if a Registration Default (as defined in the Convertible Notes, as amended) has occurred on or before March 30, 2008 and no Registration Statement has been declared effective by April 29, 2008, until the earlier to occur of the conversion of the individual Convertible Note or its maturity. There is no possible future scenario in which the accrued terminal value would not be required to be paid to the holders of the Convertible Notes or realized by such holders upon conversion of the Convertible Notes.

The Convertible Notes were not convertible until the occurrence of a conversion event, which is defined as a Convertible Note Qualified IPO described above or a qualified sale of the Company. The Company's initial public offering constituted a Convertible Note Qualified IPO.

Upon the occurrence of the Company's initial public offering, the notes plus any accrued interest thereon as well as the accreted terminal value became convertible into the Company's common stock at the option of the holder at any time from the date of the conversion event through the maturity date of the notes. The conversion price of the notes was set at \$10.01 per share upon the completion of the Company's initial public offering.

The conversion price is subject to adjustment from time to time as follows:

- i) Upon a stock dividend, stock distribution, stock split, reverse stock split or recapitalization, the conversion price shall be adjusted so that the holder of the Convertible Notes will be entitled to receive the number of shares of common stock that they would have owned if they had converted the note immediately prior to such event.
- ii) Upon a distribution of rights, options or warrants to substantially all holders of common stock entitling them to subscribe for or purchase shares of common stock for a period of time at a price per share (or having a conversion, exercise or exchange price per share) less than the current market price per share of common stock, the conversion price shall be adjusted so that the conversion price would be reduced to a price equal to the conversion price currently in effect multiplied by a fraction, the numerator of which is equal to the number of shares outstanding immediately prior to the distribution of rights, options or warrants plus the number of shares of common stock which the aggregate offering price of the total number of shares of common stock so offered (or the aggregate conversion, exercise or exchange price so offered) would purchase at the current market price per share, and the denominator of which is equal to the number of shares of common stock outstanding immediately prior to such adjustment plus the number of additional shares of common stock offered (or into which the securities so offered are convertible, exchangeable or exercisable).
- iii) Upon a distribution to all or substantially all holders of common stock any shares of capital stock of the Company (other than common stock), evidence of indebtedness or other non-cash assets, the conversion price shall be adjusted so that the conversion price would be reduced to a price equal to the conversion price currently in effect multiplied by a fraction, the numerator of which is equal to the current market price per share of the common stock on the record date of the distribution, less the fair market value per share on such record date of the capital stock, evidence of indebtedness or other non-cash assets distributed, and the denominator of which shall be the current market price per share of common stock on such record date.
- iv) Upon a cash distribution to all or substantially all holders of common stock, the conversion price shall be decreased so that the conversion price would equal the conversion price in effect multiplied by a fraction, the numerator of which is equal to the current market price per share of the common stock on the date of the distribution less the per share amount of

the distribution, and the denominator of which is the current market price per share of common stock on the date of the distribution.

- v) Upon the purchase of any shares by the Company or any of its subsidiaries by means of a tender offer, the conversion price shall be decreased so that the conversion price would equal the conversion price in effect immediately prior to the close of the tender offer, multiplied a fraction, the numerator of which is the product of the number of shares of common stock outstanding immediately prior to the closing of the tender offer multiplied by the current market price per share of the common stock, and the denominator of which shall be the sum of the aggregate consideration payable to the stockholders based on the acceptance of the tender offer and the product of the number of shares of common stock outstanding immediately prior to the close of the tender offer and the current market price per share of common stock.

Beginning on the date that is 180 days following the closing of a Convertible Note Qualified IPO, the Company may, at its option, redeem the Convertible Notes in whole at any time or in part from time to time, upon 15 days prior written notice to the holder, at a redemption price payable in cash, equal to the principal amount plus any interest (including the terminal value) accrued and unpaid, subject to the satisfaction of the following conditions precedent:

- (a) the declaration of effectiveness of a registration statement filed with the SEC for the resale of the underlying shares;
- (b) the average of the high and low sale price of the common stock, as reported on the principal securities exchange on which the common stock is listed, on each of any 20 trading days during any period of 30 consecutive trading days ending within 45 days prior to the Redemption Date (so long as, during the entire 30 trading day period, the aforementioned registration statement has been effective and there has been no suspension of trading of the common stock), having been equal to or greater than 140% of the initial public offering price in the Convertible Notes Qualified IPO (in each case, with prices adjusted for stock splits, reverse splits, stock dividends, share combination and other antidilution events); and
- (c) no more than \$12,500,000 of outstanding Convertible Notes may be redeemed pursuant to this provision in any period of 30 consecutive trading days; and
- (d) any such redemption shall be effected on a pro rata basis with respect to all then outstanding Convertible Notes (including PIK Notes).

### **13. License Agreements**

Effective July 2002, the Company entered into a patent license agreement (the Agreement) to license certain intellectual property to be used in the Company's products. The term of the Agreement is from July 2002 through April 2011. The Agreement provided for the Company to pay the licensor a \$150,000 nonrefundable license fee payable in six payments of \$25,000 each through July 2003. In connection with the license agreement, the Company agreed to issue the licensor warrants to purchase 3,125 shares of the Company's common stock, at \$32.00 per share during February 2003. The warrants were valued using the Black Scholes fair value pricing model and the resulting expense was de minimis. Such warrants were set to expire in 2008. The Agreement also provided for the Company to pay unit royalties to the licensor at specific rates as defined in the Agreement. Royalties paid during the years ended December 31, 2006, and 2005 were \$7,488, and \$3,753, respectively.

During October 2006, the Agreement was amended to provide for the Company to pay the licensor a nonrefundable license fee payable in thirteen payments of \$10,000 each through December 2007. The original warrants issued were cancelled and the licensor was issued warrants to purchase 4,687 shares of the Company's common stock at \$12.96 per share. These warrants were valued using the Black Scholes fair value pricing model and the total fair value of \$16,055 will be recognized as expense over the remaining 54 month term of the agreement. Total expense related to the warrants of \$892 and \$5,352 was recognized for the years ended December 31, 2006 and 2007, respectively.

Such warrants expire in October 2011. The amended agreement also provides for the Company to pay unit royalties to the Licensor at 5% of the net selling price of certain products sold by the Company. Such royalties may be reduced by the amount of any damages assessed against the Company resulting from claims that the licensed technology infringes upon the intellectual property rights of any third party. No royalties were paid under the amended agreement for the year ended December 31, 2007 and 2006.

#### 14. Retirement Plan

The Company has a defined contribution 401(k) plan, which covers substantially all employees. Employees can join the 401(k) plan after six months of employment. Contributions may be determined annually by the Company based on the total compensation of eligible participants and the profitability of the Company. All contributions vest immediately, whether contributed by the Company or the employee. Employees may elect to contribute up to 15% of their annual compensation up to the maximum allowable under the Internal Revenue Code. The Company did not contribute to the 401(k) plan during the years ended December 31, 2005, 2006, or 2007.

#### 15. Interim Consolidated Financial Information (Unaudited)

	Fiscal 2007 Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Revenues .....	\$ 1,815	\$ 2,378	\$ 1,701	\$ 1,918
Gross profit .....	—	—	—	—
Net loss .....	(5,950)	(7,874)	(8,269)	(14,752)
Accretion of preferred stock .....	(2,263)	(2,272)	(2,259)	(756)
Net loss applicable to common shares .....	(8,213)	(10,146)	(10,528)	(15,508)
Basic and diluted net loss per share .....	\$ (2.19)	\$ (2.68)	\$ (2.77)	\$ (1.21)
Shares used in computation of basic and diluted net loss per share .....	3,758,167	3,782,730	3,805,800	12,868,241

	Fiscal 2006 Quarter Ended			
	March 31	June 30	September 30	December 31
	(in thousands, except per share data)			
Revenues .....	\$ 2,568	\$ 1,953	\$ 1,522	\$ 1,838
Gross profit .....	—	—	—	—
Net loss .....	(5,887)	(6,914)	(6,677)	(8,853)
Accretion of preferred stock .....	(1,399)	(1,418)	(2,030)	(2,261)
Net loss applicable to common shares .....	(7,286)	(8,332)	(8,707)	(11,114)
Basic and diluted net loss per share .....	\$ (1.94)	\$ (2.22)	\$ (2.32)	\$ (2.96)
Shares used in computation of basic and diluted net loss per share .....	3,751,970	3,755,457	3,757,543	3,757,746

**Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.***

None.

**Item 9A. *Controls and Procedures.***

**1. *Disclosure Controls and Procedures***

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as December 31, 2007. Based on that evaluation, our chief executive officer and chief financial officer concluded that, as of December 31, 2007, our disclosure controls and procedures were ineffective, due to the following material weakness in our internal control over financial reporting that has not been fully remediated as of December 31, 2007:

Our management has determined that we have a material weakness in our internal control over financial reporting related to not having a sufficient number of personnel with the appropriate level of experience and technical expertise to appropriately resolve non-routine and complex accounting matters or to evaluate the impact of new and existing accounting pronouncements on our consolidated financial statements while completing the financial statement close process. The material weakness resulted in the identification of adjustments during the financial statement close process in 2007 that have been recorded in the consolidated financial statements. Until this design deficiency in our internal control over financial reporting is remediated, there is a reasonable possibility that a material misstatement to our annual or interim consolidated financial statements could occur and not be prevented or detected by our internal controls in a timely manner.

Our efforts to remediate this material weakness in our internal controls over financial reporting through the hiring and training of additional qualified financial and accounting personnel are currently in process, and consist of the following:

- we are actively seeking additional accounting and finance staff members to augment our current staff and to improve the effectiveness of our financial statement close process; and
- we will also expand the training and education of our accounting and finance staff members in an effort to improve their effectiveness.

**2. *Internal Control over Financial Reporting***

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting or an attestation report of our registered public accounting firm, due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. However, as a result of the material weakness described above, our management has concluded that our internal control over financial reporting was not effective at that date.

There was no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. *Other information.***

On January 23, 2008, Kenneth S. Abramowitz, one of our Class I directors whose term of office will expire at our 2008 annual meeting of stockholders, notified us that he does not intend to stand for re-election as a director at our 2008 annual meeting of stockholders.

### **PART III**

#### **Item 10. *Directors, Executive Officers and Corporate Governance.***

The information required under this Item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A with respect to our annual meeting of stockholders to be held on or about May 14, 2008, to be filed with the Commission not later than April 29, 2008 (the "2008 Proxy Statement") under the headings "Classes of the Board of Directors," "Director Nominees," "Directors Whose Term Extends Beyond the 2008 Annual Meeting," "Executive Officers," "Board of Directors and Director Independence," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Committees of the Board of Directors."

We have adopted a Code of Ethics that applies to all of our directors, officers and employees, including our principal executive officer and principal financial officer. The Code of Ethics is posted on our website at <http://investor.pmi2.com/governance.cfm> under the caption "Code of Ethics."

We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding any amendment to, or waiver of, a provision of our Code of Ethics by posting such information on our website, at the address and location specified above and, to the extent required by the listing standards of the Nasdaq Stock Market, by filing a Current Report on Form 8-K with the SEC, disclosing such information.

#### **Item 11. *Executive Compensation.***

The information required under this Item is incorporated herein by reference to our 2008 Proxy Statement under the heading "Executive Officers and Compensation of Executive Officers," "Director Compensation" and "Compensation Committee Interlocks and Insider Participation."

#### **Item 12. *Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The information required under this Item is incorporated herein by reference to our 2008 Proxy Statement under the heading "Information About Common Stock Ownership and Performance" and "Equity Compensation Plan Information."

#### **Item 13. *Certain Relationships and Related Transactions and Director Independence.***

The information, if any, required under this Item is incorporated herein by reference to our 2008 Proxy Statement under the headings "Certain Relationships and Related Party Transactions" and "Board of Directors and Director Independence."

#### **Item 14. *Principal Accountant Fees and Services.***

The information required under this Item is incorporated herein by reference to our 2008 Proxy Statement under the heading "Fees for Professional Services" and "Pre-Approval Policies and Procedures."



## PART IV

### Item 15. *Exhibits, Financial Statement Schedules, and Reports on Form 8-K.*

#### (a)(1) *Financial Statements*

The following financial statements are included in Item 8:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm .....	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006 .....	F-3
Consolidated Statements of Operations for the years ended December 31, 2007, 2006 and 2005 .....	F-4
Consolidated Statements of Redeemable Convertible Preferred Stock and Shareholders' Equity (Deficit) for the years ended December 31, 2007, 2006 and 2005 .....	F-5
Consolidated Statements of Cash Flows for the years ended December 31, 2007, 2006 and 2005 .....	F-6
Notes to Consolidated Financial Statements .....	F-7

#### (a)(2) *Financial Statement Schedules*

Financial statement schedules have been omitted since the required information is not present, or not present in amounts sufficient to require filing of the schedule, or because information required is included in the consolidated financial statements or the notes thereto.

#### (a)(3) *Exhibits*

The following exhibits are included in this Annual Report on Form 10-K:

Exhibit No.	Description	Filed with this Registration Statement	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
3.1	Fourth Amended and Restated Certificate of Incorporation of Power Medical Interventions, Inc.		S-1	October 5, 2007	3.2
3.2	Amended and Restated By-Laws of Power Medical Interventions, Inc.		S-1	October 5, 2007	3.4
4.1	Specimen certificate for common stock of Power Medical Interventions, Inc.		S-1	October 5, 2007	4.1
4.2	Form of Common Stock Purchase Warrant issued on October 22, 1999		S-1	May 14, 2007	4.2
4.3	Form of Common Stock Purchase Warrant issued on April 30, 2003, January 9, 2004, March 3, 2004, and April 6, 2004		S-1	May 14, 2007	4.3
4.4	Form of Common Stock Purchase Warrant issued to the Gerald and Myra S. Revocable Trust on 6/26/06		S-1	May 14, 2007	4.4

Exhibit No.	Description	Filed with this Registration Statement	Incorporated by Reference	
			Form	Filing Date
4.5	Form of Common Stock Purchase Warrant issued on June 26, 2006 and August 9, 2006		S-1	May 14, 2007
4.6	Third Amended and Restated Investors' Rights Agreement, dated June 26, 2006, by and among Power Medical Interventions, Inc. and certain of its stockholders.		S-1	May 14, 2007
4.7	Form of 7% Convertible Senior Secured Promissory Note, issued on March 30, 2007		S-1	May 14, 2007
4.8	Securities Purchase Agreement, dated March 30, 2007, by and among Power Medical Interventions, Inc and the Purchasers of 7% Convertible Senior Secured Promissory Note Named Therein		S-1	May 14, 2007
4.9	Security Agreement, dated March 30, 2007, by and among Power Medical Interventions, Inc. and the Purchasers of 7% Convertible Senior Secured Promissory Note Named Therein		S-1	May 14, 2007
4.10	Registration Rights Agreement, dated March 30, 2007, by and among Power Medical Interventions, Inc. and the Purchasers of 7% Convertible Senior Secured Promissory Note Named Therein		S-1	May 14, 2007
4.11	Amendment to Notes and Registration Rights Agreement, dated January 28, 2008, by and among Power Medical Interventions, Inc. and the Holders of 7% Senior Secured Convertible Notes due 2010 (without exhibits).		8-K	February 1, 2008
4.12	Power Medical Interventions, Inc. 2000 Stock Option Plan and form of agreements related thereto		S-1	May 14, 2007
4.13	Power Medical Interventions, Inc. 2004 Stock Incentive Plan and forms of agreements related thereto		S-1	May 14, 2007
4.14	Power Medical Interventions, Inc. 2007 Equity Incentive Plan		S-1	May 14, 2007
4.15	Power Medical Interventions, Inc. 2007 Employee Stock Purchase Plan		S-1	May 14, 2007
10.1	Underwriting Agreement, dated October 25, 2007, by and among Power Medical Interventions, Inc. and Jefferies & Company, Inc., Lazard Capital Markets LLC and William Blair & Company L.L.C., as representatives of the several underwriters named in <u>Schedule A</u> (exhibits omitted).		8-K	October 30, 2007

Exhibit No.	Description	Filed with this Registration Statement	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.2	Machinery and Equipment Loan Fund Loan Agreement, dated December 21, 2005, by and between Power Medical Interventions, Inc. and The Commonwealth of Pennsylvania, acting by and through the Department of Community and Economic Development		S-1	May 14, 2007	10.1
10.3	Machinery and Equipment Loan Fund Note, dated December 21, 2005, by Power Medical Interventions, Inc., as maker, and The Commonwealth of Pennsylvania, acting by and through the Department of Community and Economic Development, as payee		S-1	May 14, 2007	10.2
10.4	Machinery and Equipment Loan Fund Security Agreement, dated December 21, 2005, by and between Power Medical Interventions, Inc. and The Commonwealth of Pennsylvania, acting by and through the Department of Community and Economic Development		S-1	May 14, 2007	10.3
10.5	Second Amended and Restated Employment Agreement by and between Power Medical Interventions, Inc. and Michael P. Whitman dated March 23, 2007 (Confidential treatment for portions of this agreement has been granted pursuant to Rule 406. A copy of the agreement including the confidential portions has been filed with the Securities and Exchange Commission.)		S-1	May 14, 2007	10.4
10.6	First Amendment to Second Amended and Restated Employment Agreement by and between Power Medical Interventions, Inc. and Michael P. Whitman dated February 4, 2008 (Confidential treatment for portions of this agreement has been requested pursuant to Rule 24b-2. A copy of the agreement including the confidential portions has been filed with the Securities and Exchange Commission.)	X			
10.7	Employment Agreement by and between Power Medical Interventions, Inc. and John P. Gandolfo dated January 5, 2007.		S-1	May 14, 2007	10.5

Exhibit No.	Description	Filed with this Registration Statement	Incorporated by Reference		
			Form	Filing Date	Exhibit No.
10.8	First Amendment to Employment Agreement by and between Power Medical Interventions, Inc. and John P. Gandolfo, dated February 4, 2008 (Confidential treatment for portions of this agreement has been requested pursuant to Rule 24b-2. A copy of the agreement including the confidential portions has been filed with the Securities and Exchange Commission.).	X			
21.1	List of Subsidiaries		S-1	May 14, 2007	21.1
31.1	Certification of the Chief Executive Officer required by Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
31.2	Certification of the Chief Financial Officer required by Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934, as amended as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X			
32.1	Certification of the Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			
32.2	Certification of the Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X			

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, as of March 31, 2008.

### POWER MEDICAL INTERVENTIONS, INC.

By: /s/ Michael P. Whitman

Michael P. Whitman  
President and Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1934, this registration statement has been signed by the following person in the capacity and on the date indicated.

/s/ MICHAEL P. WHITMAN

Michael P. Whitman	President and Chief Executive Officer ( <i>principal executive officer</i> )	March 31, 2008
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/s/ JOHN P. GANDOLFO

John P. Gandolfo	Chief Financial Officer ( <i>principal financial officer and principal accounting officer</i> )	March 31, 2008
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/s/ KENNETH S. ABRAMOWITZ

Kenneth S. Abramowitz	Director	March 31, 2008
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/s/ JAMES R. LOCHER III

James R. Locher III	Director	March 31, 2008
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/s/ JOHN C. MORAN

John C. Moran	Director	March 31, 2008
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/s/ LON E. OTREMBA

Lon E. Otremba	Director	March 31, 2008
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# **POWER MEDICAL INTERVENTIONS, INC.**

**2021 CABOT BOULEVARD  
LANGHORNE, PENNSYLVANIA 19047  
(267) 775-8100**

## **NOTICE OF SPECIAL MEETING IN LIEU OF ANNUAL MEETING OF STOCKHOLDERS TO BE HELD ON MAY 14, 2008**

To the Stockholders of Power Medical Interventions, Inc.:

Notice is hereby given that a Special Meeting in Lieu of Annual Meeting of Stockholders (the "*Annual Meeting*") of Power Medical Interventions, Inc., a Delaware corporation ("*PMI*" or the "*Company*"), will be held at 10:00 a.m., local time, on May 14, 2008, at the Inn at Lambertville Station, 11 Bridge Street, Lambertville, New Jersey 08530, to consider and act upon the following proposals:

1. To elect two members to the board of directors to serve for three-year terms as Class I directors;
2. To approve an amendment to our 2007 equity incentive plan increasing the shares of our common stock issuable under the plan by 945,164 shares;
3. To ratify the selection of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2008; and
4. To transact such other business as may properly come before the Annual Meeting or any postponements or adjournments thereof.

The board of directors has fixed the close of business on March 31, 2008, as the record date for the determination of the PMI stockholders entitled to notice of, and to vote at, the Annual Meeting and any postponements or adjournments thereof.

All stockholders are cordially invited to attend the Annual Meeting in person. HOWEVER, TO ENSURE YOUR REPRESENTATION AT THE ANNUAL MEETING, YOU ARE URGED TO COMPLETE, SIGN AND RETURN THE ENCLOSED PROXY CARD AS PROMPTLY AS POSSIBLE IN THE ENCLOSED POSTAGE-PREPAID ENVELOPE. You may revoke your proxy in the manner described in the accompanying Proxy Statement at any time before it has been voted at the Annual Meeting. Any stockholder attending the Annual Meeting may vote in person even if he or she has returned a proxy.

Properly executed proxies will be voted in accordance with the specifications on the proxy card. A list of stockholders entitled to vote will be available for inspection at the offices of the Company, located at 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047, for a period of ten (10) days prior to the Annual Meeting. Executed proxies with no instructions indicated thereon will be voted FOR the election of management's nominees for director and FOR approval of the other matters set forth in this Notice of Annual Meeting of Stockholders.

By Order of the Board of Directors,



Elizabeth McLoughlin  
*Secretary*

Langhorne, Pennsylvania  
April 16, 2008

**YOUR VOTE IS IMPORTANT. WHETHER OR NOT YOU PLAN TO ATTEND THE ANNUAL MEETING, PLEASE COMPLETE, SIGN AND DATE THE ENCLOSED PROXY CARD AND RETURN IT AS PROMPTLY AS POSSIBLE IN THE ENCLOSED POSTAGE-PREPAID ENVELOPE.**



## POWER MEDICAL INTERVENTIONS, INC.

May 14, 2008

**VOTE BY INTERNET OR TELEPHONE**  
**QUICK ★★★ EASY ★★★ IMMEDIATE**

**Electronic Voting Instructions**

You can vote via Internet or by telephone. Instead of mailing your proxy, you may choose one of two voting methods outlined below to vote your proxy electronically. You may also vote in person at the meeting. Votes submitted by Internet or by telephone must be received by 7:00 p.m., eastern daylight savings time, May 13, 2008.

**Vote Your Proxy on the Internet:**

Go to [www.continentalstock.com](http://www.continentalstock.com)  
 Have your proxy card available when you access the above website. Follow the prompts to vote your shares.

OR

**Vote Your Proxy by Phone:**

Call 1 (866) 894-0537

Use any touch-tone telephone to vote your proxy. Have your proxy card available when you call. Follow the voting instructions to vote your shares.

OR

**Vote Your Proxy by mail:**

Mark, sign, and date your proxy card, then detach it, and return it in the postage-paid envelope provided.

**PLEASE DO NOT RETURN THE PROXY CARD IF YOU ARE  
 VOTING ELECTRONICALLY OR BY PHONE**

▼ FOLD AND DETACH HERE AND READ THE REVERSE SIDE ▼

**PROXY**

THE BOARD OF DIRECTORS RECOMMENDS A VOTE "FOR" THE ELECTION OF ALL NOMINEES FOR DIRECTOR AND "FOR" PROPOSAL 2 AND PROPOSAL 3.

Please mark your votes like this



FOR all nominees listed to the left    WITHHOLD AUTHORITY to vote for all nominees listed to the left    FOR ALL EXCEPT (See instructions below)

☐
☐
☐

1. Election of two Class I Directors for a three-year term.

NOMINEES: (01) Charles W. Federico  
 (02) David R. Murray

2. To approve the amendment to the 2007 Equity Incentive Plan.

FOR    AGAINST    ABSTAIN  
☐    ☐    ☐

3. To ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm.

FOR    AGAINST    ABSTAIN  
☐    ☐    ☐

(Instruction: To withhold authority to vote for any individual nominee, mark "FOR ALL EXCEPT" and strike a line through that nominee's name in the list above)

THIS PROXY WHEN PROPERLY EXECUTED WILL BE VOTED AS INDICATED. IF NO CONTRARY INDICATION IS MADE, THE PROXY WILL BE VOTED IN FAVOR OF ELECTING THE TWO NOMINEES TO THE BOARD OF DIRECTORS, AND FOR PROPOSALS 2 AND 3, AND IN ACCORDANCE WITH THE JUDGMENT OF THE PERSONS NAMED AS PROXY HEREIN, ON ANY OTHER MATTERS THAT MAY PROPERLY COME BEFORE THE ANNUAL MEETING. THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS.

COMPANY ID:

PROXY NUMBER:

ACCOUNT NUMBER:

Signature \_\_\_\_\_ Signature \_\_\_\_\_ Date \_\_\_\_\_, 2008.

Note: Please sign exactly as your name or names appear on this Proxy. When shares are held jointly, each holder should sign. When signing as executor, administrator, attorney, trustee or guardian, please give full title as such. If the signer is a corporation, please sign full corporate name by duly authorized officer, giving full title as such. If signer is a partnership, please sign in partnership name by authorized person.

▼ FOLD AND DETACH HERE AND READ THE REVERSE SIDE ▼

**PROXY**

**POWER MEDICAL INTERVENTIONS, INC.**

**2021 Cabot Boulevard  
Langhorne, Pennsylvania 19047**

**THIS PROXY IS SOLICITED ON BEHALF OF THE BOARD OF DIRECTORS**

The undersigned hereby appoints Michael P. Whitman and John P. Gandolfo as proxies, each with full power of substitution, to represent and vote as designated on the reverse side, all the shares of Common Stock of Power Medical Interventions, Inc. held of record by the undersigned on March 31, 2008, at the Special Meeting in Lieu of Annual Meeting of Stockholders to be held at the Inn at Lambertville Station, 11 Bridge Street, Lambertville, New Jersey 08530, on May 14, 2008, at 10:00 a.m. local time, or any adjournment or postponement thereof.

**(Continued, and to be marked, dated and signed, on the other side)**

**POWER MEDICAL INTERVENTIONS, INC.**  
2021 CABOT BOULEVARD  
LANGHORNE, PENNSYLVANIA 19047  
(267) 775-8100

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**PROXY STATEMENT**  
**2008 ANNUAL MEETING OF STOCKHOLDERS**  
To Be Held May 14, 2008

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**Table of Contents**

	<u>Page</u>
<b>INFORMATION ABOUT THE MEETING</b>	
The Meeting .....	1
How to Vote .....	1
Quorum and Tabulation of Votes .....	2
Multiple Stockholders Sharing the Same Address .....	3
<b>PROPOSAL ONE—ELECTION OF CLASS 1 DIRECTORS</b>	
Classes of the Board of Directors .....	4
Director Nominees .....	4
Directors Whose Term Extends Beyond the 2008 Annual Meeting .....	5
Director Independence .....	6
Committees of the Board of Directors .....	6
Compensation Committee Interlocks and Insider Participation .....	7
Director Compensation .....	7
Meetings of the Board of Directors .....	8
Policy Regarding Board Attendance .....	8
Director Candidates and Selection Process .....	9
Stockholder Communications with the Board .....	9
Code of Ethics .....	10
Board of Directors' Recommendation .....	10
<b>PROPOSAL TWO—AMENDMENT TO OUR 2007 EQUITY INCENTIVE PLAN</b>	
Description of Amendment to Our 2007 Equity Incentive Plan .....	11
Description of Our 2007 Equity Incentive Plan .....	12
New Plan Benefits .....	13
Future Amendments to the 2007 Equity Incentive Plan .....	13
Other Equity Incentive Plans .....	14
Board of Directors' Recommendation .....	15
<b>PROPOSAL THREE—RATIFICATION OF APPOINTMENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</b>	
Board of Directors' Recommendation .....	16

	<u>Page</u>
<b>EXECUTIVE OFFICERS AND COMPENSATION OF EXECUTIVE OFFICERS</b>	
Executive Officers .....	17
Compensation Discussion and Analysis .....	18
Equity Compensation Plan Information .....	27
Compensation Committee Report .....	28
<b>INFORMATION ABOUT COMMON STOCK OWNERSHIP AND PERFORMANCE</b>	
Stock Owned by Directors, Executive Officers and Greater-Than-5% Stockholders .....	29
Section 16(a) Beneficial Ownership Reporting Compliance .....	31
<b>INFORMATION ABOUT OUR AUDIT COMMITTEE AND AUDITORS</b>	
Our Auditors .....	32
Audit Committee Report .....	32
Fees for Professional Services .....	33
Pre-Approval Policies and Procedures .....	33
Whistleblower Procedures .....	33
<b>CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS</b>	
Policies and Procedures .....	34
Transactions with Gerald Dorros, M.D. ....	34
<b>OTHER MATTERS</b>	
Other Business .....	35
Stockholder Proposals .....	35
Nomination of Director Candidates .....	35
Where You Can Find Additional Information .....	35

**POWER MEDICAL INTERVENTIONS, INC.**  
2021 CABOT BOULEVARD  
LANGHORNE, PENNSYLVANIA 19047  
(267) 775-8100

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**PROXY STATEMENT**  
**2008 ANNUAL MEETING OF STOCKHOLDERS**  
**To Be Held May 14, 2008**

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**INFORMATION ABOUT THE MEETING**

***The Meeting***

This Proxy Statement is being furnished in connection with the solicitation of proxies by the board of directors of Power Medical Interventions, Inc., a Delaware corporation ("**PMI**" or the "**Company**"), for use at the Company's Special Meeting in Lieu of Annual Meeting of Stockholders to be held on Wednesday, May 14, 2008 (the "**Annual Meeting**") at 10:00 a.m., local time, at the Inn at Lambertville Station, 11 Bridge Street, Lambertville, New Jersey 08530, or at any postponements or adjournments thereof. The purpose of the Annual Meeting is to consider and act upon the following proposals:

1. To elect two members to our board of directors to serve for three-year terms as Class I directors;
2. To approve an amendment to our 2007 equity incentive plan increasing the shares of our common stock issuable under the plan by 945,164 shares;
3. To ratify the selection of Ernst & Young LLP as our independent auditors for the fiscal year ending December 31, 2008; and
4. To transact such other business as may properly come before the Annual Meeting or any postponements or adjournments thereof.

This Proxy Statement and the enclosed proxy card, as well as our annual report, containing financial statements and management's discussion and analysis of financial condition and results of operations for the twelve months ended December 31, 2007, will be mailed to stockholders on or about April 16, 2008.

***How to Vote***

Only stockholders of record at the close of business on March 31, 2008 (the "**Record Date**") will be entitled to notice of, and to vote at, the Annual Meeting or any adjournment thereof. As of the Record Date, an aggregate of 17,107,052 shares of common stock, \$0.001 par value per share (the "**Common Stock**"), of the Company were issued and outstanding and held by approximately 525 holders of record. The holders of Common Stock are entitled to one vote per share on any proposal presented at the Annual Meeting. Stockholders may vote in person or by proxy. Instead of submitting a signed proxy card, stockholders may submit their proxies by telephone or through the Internet. Telephone and Internet proxies must be used in conjunction with, and will be subject to, the information and terms contained on the form of proxy. Similar procedures may also be available to stockholders who hold their shares through a broker, nominee, fiduciary or other custodian. Execution of a proxy will not in any way affect a stockholder's right to attend the Annual Meeting and vote in person. Any proxy may be revoked by the person giving it at any time before its exercise by (1) filing with the Secretary of the

Company, before the taking of the vote at the Annual Meeting, a written notice of revocation bearing a later date than the proxy, (2) duly executing a later dated proxy relating to the same shares and delivering it to the Secretary of the Company before the taking of the vote at the Annual Meeting, or (3) attending the Annual Meeting and voting in person (although attendance at the Annual Meeting will not in and of itself constitute a revocation of a proxy). Any written notice of revocation or subsequent proxy should be sent to Power Medical Interventions, Inc., 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047, Attention: Corporate Secretary, at or before the taking of the vote at the Annual Meeting.

#### *Quorum and Tabulation of Votes*

Our bylaws provide that the representation in person or by proxy of at least a majority of the outstanding shares of Common Stock entitled to vote at the Annual Meeting is necessary to establish a quorum for the transaction of business at the Annual Meeting. If, however, a quorum is not present, in person or represented by proxy, then either the chairman of the meeting or the stockholders entitled to vote at the meeting may adjourn the meeting until a later time. Abstentions and broker "non-votes" are counted as present or represented for purposes of determining the presence or absence of a quorum. A broker "non-vote" occurs when a broker holding shares for a beneficial owner votes on one proposal, but does not vote on another proposal because, in respect of such other proposal, the broker does not have discretionary voting power and has not received instructions from the beneficial owner. The election of directors and the ratification of the appointment of independent registered public accounting firms are considered routine matters and under the rules that currently govern brokers and banks, brokers will have discretion to vote shares held in street name for their clients on those matters. Approval of the amendment to our 2007 equity incentive plan is considered non-routine, and therefore, without instructions from their clients, brokers and banks will not have discretion to vote their clients' shares on that matter.

The election of directors requires a plurality of the votes cast for the election of directors and, accordingly, the two director nominees receiving the highest number of "FOR" votes at the meeting will be elected to serve as Class I directors. You may vote either "FOR" or "WITHHOLD" your vote for each director nominee. A properly executed proxy marked "WITHHOLD" with respect to the election of one or more directors will not be voted with respect to the director or directors indicated, although it will be counted for purposes of determining whether there is a quorum.

Under our bylaws, the approval of the amendment to the 2007 equity incentive plan requires a majority of the votes cast. You may vote either "FOR" or "AGAINST" approval of the amendment to the 2007 equity incentive plan, or you may abstain. A properly executed proxy marked "ABSTAIN" with respect to the approval of the amendment to the 2007 equity incentive plan will not be counted as a vote cast with respect to that proposal.

Stockholder ratification of the appointment of Ernst & Young LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2008 is not required by law or by our governing instruments. However, our board of directors is submitting the selection of Ernst & Young LLP to our stockholders for ratification as a matter of good corporate governance and practice. Under our bylaws, the ratification of the appointment of Ernst & Young LLP requires a majority of the votes cast. You may vote either "FOR" or "AGAINST" ratification of the appointment, or you may abstain. A properly executed proxy marked "ABSTAIN" with respect to the ratification of the appointment will not be counted as a vote cast with respect to such ratification.

The only items of business that our board of directors intends to present at the meeting are set forth in this proxy statement. As of the date of this proxy statement, no stockholder has advised us of an intent to present any other matter, and we are not aware of any other matters to be presented at the meeting. If any other matter or matters are properly brought before the meeting, the person(s)

named as your proxyholder(s) will have the discretion to vote your shares on those matters in accordance with their best judgment and as they deem advisable.

An automated system administered by the Company's transfer agent tabulates the votes. The vote on each matter submitted to stockholders is tabulated separately. Abstentions and broker "non-votes" are not counted as votes cast for the particular matter and have the effect of reducing the number of affirmative votes required to achieve a majority for such matter by reducing the total number of shares from which the majority is calculated.

The persons named as attorneys-in-fact in the proxies were selected by our board of directors and are officers of the Company. All properly executed proxies returned in time to be counted at the Annual Meeting will be voted.

**All shares represented by properly executed proxies will be voted in accordance with the stockholders' instructions, and if no choice is specified, the shares represented by proxies will be voted in favor of the proposals set forth in the accompanying Notice of Special Meeting in Lieu of Annual Meeting.**

***Multiple Stockholders Sharing the Same Address***

If you and other residents at your mailing address own shares of Common Stock through a broker or other nominee, you may have elected to receive only one copy of this proxy statement and our 2007 Annual Report. If you and other residents at your mailing address own shares of Common Stock in your own names, you may have received only one copy of this proxy statement and our 2007 Annual Report unless you provided our transfer agent with contrary instructions.

This practice, known as "householding," is designed to reduce our printing and postage costs. You may promptly obtain an additional copy of this proxy statement, enclosed proxy card and our 2007 Annual Report by sending a written request to Power Medical Interventions, Inc., 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047, Attention: Corporate Secretary. If you hold your shares through a broker or other nominee and wish to discontinue householding or to change your householding election, you may do so by calling (800) 542-1061 or writing to Broadridge Financial Solutions, Household Department, 51 Mercedes Way, Edgewood, New York 11717. If you hold shares in your own name and wish to discontinue householding or change your householding election, you may do so by calling (212) 509-4000 or writing to Continental Stock Transfer & Trust Company, 17 Battery Place, New York, New York 10004.

## PROPOSAL ONE—ELECTION OF CLASS I DIRECTORS

Our board of directors has fixed the number of directors at seven pursuant to our bylaws. The terms of office of our Class I directors expire on the date of the 2008 Annual Meeting. Our Class I director Kenneth S. Abramowitz has notified us that he does not intend to seek re-election at our 2008 Annual Meeting. Our board of directors has nominated David R. Murray for re-election as a Class I director and has nominated Charles W. Federico for election as a Class I director to succeed Mr. Abramowitz, in each case for a three-year term expiring at our annual meeting of stockholders in 2011. Our five Class II and Class III directors will continue in office after the Annual Meeting.

### *Classes of the Board of Directors*

Our board of directors is divided into three classes. Each of the directors serves a three-year term, with one class of directors being elected by our stockholders at each annual meeting. Currently, our directors are divided into Classes I, II and III as follows:

<u>Name</u>	<u>Age</u>	<u>Term Expires</u>	<u>Position</u>
<b>CLASS I DIRECTORS</b>			
Kenneth S. Abramowitz(1) . . . . .	56	2008	Director
David R. Murray(3)(2) . . . . .	60	2008	Director
<b>CLASS II DIRECTORS</b>			
James R. Locher III(3) . . . . .	60	2009	Director
Lon E. Otremba(1)(2) . . . . .	50	2009	Director
<b>CLASS III DIRECTORS</b>			
Gerald Dorros, M.D.(2)(3) . . . . .	65	2010	Director
John C. Moran(1)(3) . . . . .	54	2010	Director
Michael P. Whitman . . . . .	47	2010	President, Chief Executive Officer and Chairman of the Board of Directors

- (1) Member of audit committee.
- (2) Member of compensation committee.
- (3) Member of nominating committee.

### *Director Nominees*

At the Annual Meeting, two Class I directors will be elected to serve until the 2011 annual meeting and until such directors' successors are duly elected and qualified, or until their earlier death, resignation, removal or disqualification. Our board of directors has nominated Charles W. Federico for election and David R. Murray for re-election as Class I directors. Both nominees have agreed to serve if elected, and we have no reason to believe that either will be unable to serve. In the event that a nominee is unable or declines to serve as a director at the time of the Annual Meeting, proxies will be voted for another nominee as is then designated by our board of directors.

*Charles W. Federico*, age 59, is currently retired. From 2001 until his retirement in 2006, Mr. Federico was President and Chief Executive Officer of Orthofix International N.V., a provider of innovative solutions for trauma and spine fusion. He also served as President of Orthofix Inc., a subsidiary of Orthofix International, from 1996 to 2002. He remains a director of Orthofix International. Prior to joining Orthofix, Mr. Federico was with Smith & Nephew Endoscopy for 16 years, where he served most recently as its President. Mr. Federico is also a member of the Board of Directors of BioMimetic Therapeutics, Inc., Mako Surgical Corp. and SRI/Surgical Express, Inc. He also currently serves on the Board of Trustees of the Orthopaedic Research and Education Foundation, and previously was a Founding Trustee and board member of the American Sports Medicine Institute.



*David R. Murray* has served as a member of our Board of Directors since October 2007. Since 2004, Mr. Murray has been President of Conmed Electrosurgery, a provider of electrosurgical instruments that is a division of Conmed Corporation. Prior to joining Conmed, Mr. Murray operated his own consulting business for nine years where he served as interim CEO in early stage medical device companies, assisting them to develop and implement strategies to drive growth and investment. From 1996 to 2001, he also served as President and Chief Executive Officer of CryoGen, Inc., a women's healthcare company. Prior to starting his consulting business Mr. Murray worked for seventeen years at Johnson & Johnson companies, in a number of roles, including Vice President of Sales and Marketing for Ethicon, Inc. and as President of Critikon. Mr. Murray holds a B.S. in Industrial Management from Purdue University and a M.B.A. in Finance from the Wharton School of the University of Pennsylvania.

***Directors Whose Term Extends Beyond the 2008 Annual Meeting***

*Michael P. Whitman* founded Power Medical Interventions, Inc. with Gerald Dorros, M.D. in October 1999 and has served as our President and Chief Executive Officer and Chairman of our Board of Directors since our inception. Before founding our company, Mr. Whitman served as Vice President of Marketing at Olympus America Inc., a manufacturer of endoscopes and medical imaging systems, from April 1998 to October 1999. He worked for several subsidiaries of Johnson & Johnson, serving as Vice President of Sales and as Director of Sales and Marketing for Cordis Endovascular from June 1995 to April 1998, Regional Sales Manager for Ethicon Endo-Surgery from September 1992 to October 1993, and Group Product Director for Ethicon, Inc. from May 1991 to September 1992. Before that he held product development positions at both Ethicon Endo-Surgery and Johnson & Johnson Interventional Systems. Mr. Whitman also served as Director of Marketing for Synthes Spine Company, LP, a provider of instruments, implants and tools for orthopedic and spine surgery, from December 1993 to June 1995. Mr. Whitman received a Bachelor of Arts degree in Business and Economics from Lafayette College.

*Dr. Gerald Dorros* co-founded our company with Mr. Whitman in 1999 and has served as a member of our Board of Directors since our inception. He is an interventional cardiologist and cardiovascular interventionist, and has served as the Medical Director of the Dorros Feuer Interventional Cardiovascular Disease Foundation Ltd., since 1983. He also served as the President of the Arizona Heart Institute Foundation from 1997 to 2000 and previously was a partner of the Milwaukee Heart and Vascular Clinic from 1981 to 1997. Dr. Dorros has held clinical professorships in medicine at the University of Wisconsin, Columbia University, State University of New York, and University of Illinois. Dr. Dorros received a Bachelor of Arts degree from Dartmouth College in 1964, and a medical degree from the Albert Einstein College of Medicine of Yeshiva University in 1968. He has received honorary Doctor of Science degrees from Yeshiva University and Colby College.

*The Honorable James R. Locher III* has been a member of our Board of Directors since 1999. Since 1993, Mr. Locher has written, lectured, consulted, and served on commissions related to the organization of the United States Department of Defense. Currently, he is serving as Executive Director of the Project on National Security Reform, an effort to reorganize the U.S. national security system. From 2003 to 2004, he served as Chairman of the Defense Reform Commission of Bosnia and Herzegovina. From 1989 to 1993, Mr. Locher was Assistant Secretary of Defense for Special Operations and Low-Intensity Conflict. From 1978 to 1986, Mr. Locher served on the staff of the Senate Armed Services Committee. He has also held staff positions in the White House and the Pentagon. He is a graduate of the United States Military Academy at West Point, received a master's degree in business administration from Harvard Business School, and was awarded an honorary Doctor of Laws degree from Hampden-Sydney College.

*John C. Moran* has been a member of our Board of Directors since 1999. Since 1997, Mr. Moran has been a private investor. From 1990 to 1997, Mr. Moran served as the first President of Synthes Spine Company, LP, an affiliate of Synthes, Inc., that makes instruments, implants and tools for orthopedic and spine surgery. From 1979 to 1990, Mr. Moran served in various capacities at Synthes USA, another affiliate of Synthes, Inc., including Vice President of Finance and Administration and Chief Operating Officer. Mr. Moran is also a member of the Board of Directors of Advanced Biomaterials Systems, Anika Therapeutics, Inc., Christini Technologies, Inc., Paradigm Spine, LLC and Rainier Technologies Corporation. Mr. Moran received a master's degree in business administration from Harvard Business School and is a graduate of the University of Notre Dame.

*Lon E. Otremba* has been a member of our Board of Directors since October 2006. Since 2005 he has been the Principal Managing Partner of Otremba Management Advisory LLC, a strategic and operational management advisory firm. Mr. Otremba also served as Chief Executive Officer and a director of Muzak, LLC, a provider of commercial music services, from 2003 to 2005. Prior to joining Muzak, Mr. Otremba served as Executive Vice President, Strategic Planning and Operations of the AOL Interactive Marketing Group of Time Warner, from 2002 to 2003, and as Executive Vice President, Strategic Planning, of the AOL Time Warner Local Partnership Group from 2001 to 2002. Mr. Otremba currently also serves on the board of directors of Artes Medical, Cardium Therapeutics, Access 360 Media, and EEI Communications. He is also a trustee and treasurer of Buckley Country Day School. Mr. Otremba holds a Bachelor of Arts degree in marketing and economics from Michigan State University.

#### ***Director Independence***

A majority of our directors are independent within the meaning of the applicable rules of the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market, LLC. Specifically, our board of directors has determined that each of Messrs. Abramowitz, Cesarek, Dorros, Locher, Moran, Otremba and Murray is an independent director, and that Mr. Federico will upon his election be an independent director.

Each executive officer serves at the discretion of the board of directors and holds office until his or her successor is elected and qualified or until his or her earlier resignation or removal. There are no family relationships among any of our directors and executive officers.

#### ***Committees of the Board of Directors***

Our board of directors has established an audit committee, a compensation committee and a nominating committee, which are the only standing committees of the board of directors.

*Audit committee.* The current members of our audit committee are John C. Moran who serves as chairman, Kenneth S. Abramowitz and Lon E. Otremba. Upon the election of Charles W. Federico as a director at the Annual Meeting, Mr. Federico will succeed Mr. Abramowitz as a member of the audit committee. The board of directors has determined that each of Messrs. Moran, Abramowitz, Otremba and Federico qualifies as an independent director for purposes of service on the audit committee, and that Mr. Moran qualifies as an "audit committee financial expert," as defined by applicable rules of The Nasdaq Stock Market, LLC and the SEC. The audit committee assists our board of directors in its oversight of:

- the integrity of our financial statements;
- our compliance with legal and regulatory requirements;
- the qualifications and independence of our independent registered public accounting firm; and
- the performance of our independent registered public accounting firm.

The audit committee has direct responsibility for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm, Ernst & Young LLP. The audit committee establishes and implements policies and procedures for the pre-approval of all audit services and all permissible non-audit services provided by our independent registered public accounting firm and reviews and approves any related party transactions entered into by us. Our audit committee met three times and acted one time by written consent during 2007.

*Compensation committee.* The current members of our compensation committee are David R. Murray, who serves as chairman, Gerald Dorros, M.D. and Lon E. Otremba, each of whom is an independent director. The compensation committee:

- recommends to the board of directors the compensation and benefits of our executive officers;
- reviews and makes recommendations to the board of directors regarding benefit plans and programs for employee compensation; and
- administers our equity compensation plans.

Our compensation committee met five times and acted seven times by written consent during 2007.

*Nominating committee.* The current members of our nominating committee are Mr. Locher, who serves as chairman, Gerald Dorros and John C. Moran, each of whom is an independent director. The nominating committee:

- identifies individuals qualified to become board members; and
- recommends to the board of directors nominations of persons to be elected to the board.

Our nominating committee did not meet or act by written consent during 2007.

*Committee Charters.* Each of our audit, compensation and nominating committees are governed by charters that have been approved by our board of directors and are publicly available on our website, [www.pmi2.com](http://www.pmi2.com), under the section "Corporate Governance."

#### ***Compensation Committee Interlocks and Insider Participation***

No member of our board of directors or our compensation committee serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

#### ***Director Compensation***

Prior to May 2007, our directors did not receive any cash compensation for their services as directors. Our non-employee directors were reimbursed, upon request, for travel and other out-of-pocket expenses incurred in connection with their attendance at meetings of the board and of committees on which they served. Some of our directors received options to purchase shares of our common stock. These options were not granted regularly and they usually vested in equal installments over four years.

In May 2007, our board of directors adopted a compensation plan for non-employee directors. Each non-employee director receives cash compensation at a rate of \$20,000 per year, or a rate of \$25,000 per year for the chairmen of our audit and compensation committees. In addition, non-employee directors are paid \$2,000 for each regularly scheduled board meeting that they attend in person or by teleconference and are reimbursed, upon request, for travel and other out-of-pocket expenses incurred in connection with their attendance at board meetings. In addition, each non-employee director who continues in office after our 2008 Annual Meeting will receive a non-qualified option to purchase 4,688 shares of our common stock. Mr. Federico would also receive a

non-qualified stock option to purchase 4,688 shares of our common stock upon his election as a director. These options will vest in equal monthly installments over three years from the date of grant. All such options shall become fully vested in the event of a change of control of our company.

The following table provides compensation information for all our non-employee directors during 2007:

	Fees earned or paid in cash(1)	Option Awards(2)	All Other Compensation(3)	Total
Kenneth S. Abramowitz . . . . .	\$12,000	\$38,207	—	\$50,207
Timothy J. Cesarek(4) . . . . .	11,725	—	—	11,725
Gerald Dorros, M.D. . . . .	12,000	38,207	\$4,134	54,341
James R. Locher III . . . . .	10,000	38,207	1,245	49,452
John C. Moran . . . . .	14,500	38,207	—	52,707
Lon E. Otremba . . . . .	14,500	38,207	—	52,707
David R. Murray . . . . .	275	38,207	—	38,482

- (1) Consists of cash compensation earned after the May 2007 adoption of our director compensation plan, prorated for the director's term of service, and a board meeting fee of \$2,000 for each regularly scheduled board meeting attended by the director.
- (2) Amounts shown do not reflect compensation actually received by the director. The amounts shown represent expense recognized in our 2007 consolidated financial statements in accordance with SFAS 123(R) for option awards granted to our directors, except that we have disregarded any estimate of future forfeitures related to service-based vesting conditions with respect to such option awards. Except for the forfeiture of stock options to purchase 391 shares of our common stock held by our former director, Timothy Cesarek, there were no actual forfeitures of stock options by any director in 2007. The other assumptions used to calculate the expense amounts shown for stock options granted in 2007 are set forth in Note 2 to the consolidated financial statements included in our Annual Report on Form 10-K filed with the SEC on March 31, 2008.
- (3) Consists of travel and other out-of-pocket expenses incurred in connection with attendance at board meetings.
- (4) Mr. Cesarek resigned from our board of directors effective upon the closing of our initial public offering on October 31, 2007. Upon his resignation Mr. Cesarek forfeited options to purchase 391 shares of our common stock. Mr. Cesarek's remaining options to purchase 4,297 shares expired on January 31, 2008.

#### ***Meetings of the Board of Directors***

Our board of directors met in person or by telephone nine times and acted by unanimous written consent four times during the year ended December 31, 2007. All of our directors attended at least 75% of the aggregate of the total number of meetings of the board of directors and meetings held by all committees of the board on which they served in 2007.

#### ***Policy Regarding Board Attendance***

Our directors are expected to attend meetings of the board of directors and meetings of committees on which they serve. Our directors are expected to spend the time needed at each meeting and to meet as frequently as necessary to properly discharge their responsibilities. We encourage

members of our board of directors to attend annual meetings of stockholders, but we do not have a formal policy requiring them to do so.

#### ***Director Candidates and Selection Process***

Our nominating committee, in consultation with our chief executive officer, is responsible for identifying and reviewing candidates to fill open positions on the board of directors, including positions arising as a result of the expiration of the term, removal, resignation or retirement of any director, an increase in the size of the board or otherwise, and recommending to our full board candidates for nomination for election to the board. In recommending new directors, the committee will consider any requirements of applicable law or listing standards, a candidate's strength of character, judgment, business experience and specific area of expertise, factors relating to the composition of the board (including its size and structure), principles of diversity, and such other factors as the committee deems to be appropriate.

The committee is responsible for reviewing from time to time the appropriate skills and characteristics required of board members in the context of the current make-up of the board, including such factors as business experience, diversity, and personal skills in technology, finance, marketing, sales, operations and other areas that contribute to an effective board.

Stockholders may recommend individuals to the nominating committee for consideration as potential director candidates by submitting their names, together with appropriate biographical information and background materials and a statement as to whether the stockholder or group of stockholders making the recommendation has beneficially owned more than 5% of our common stock for at least a year as of the date such recommendation is made, to our nominating committee, c/o Corporate Secretary, Power Medical Interventions, Inc., 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047. Assuming that appropriate biographical and background material has been provided on a timely basis, the nominating committee will evaluate stockholder-recommended candidates by following substantially the same process, and applying substantially the same criteria, as it follows for candidates submitted by others. If the board determines to nominate a stockholder-recommended candidate and recommends his or her election, then his or her name will be included in our proxy card for the next annual meeting. Any recommendation of a potential director nominee should also include a statement signed by the proposed nominee expressing a willingness to serve on our board if elected. As part of this responsibility, the committee will be responsible for conducting, subject to applicable law, any and all inquiries into the background and qualifications of any candidate for the board and such candidate's compliance with the independence and other qualification requirements established by the committee or imposed by applicable law or listing standards.

#### ***Stockholder Communications with the Board***

Stockholders wishing to communicate with our board of directors should send correspondence to the attention of the Chairman of the Board of Directors, c/o Corporate Secretary, Power Medical Interventions, Inc., 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047, and should include with the correspondence evidence that the sender of the communication is one of our stockholders. Satisfactory evidence would include, for example, contemporaneous correspondence from a brokerage firm indicating the identity of the stockholder and the number of shares held. The chairman will review all correspondence confirmed to be from stockholders and decide whether or not to forward the correspondence or a summary of the correspondence to the full board of directors or a committee of the board, or if the chairman determines in accordance with his best judgment that the matter can be addressed by management, then to the appropriate officer of the Company. The chairman will review all stockholder correspondence, but the decision to relay that correspondence to the full board or a committee will rest entirely within his discretion. Our board of directors believes that this process will suffice to handle the relatively low volume of communications we have historically received from our stockholders. If the volume of communications increases such that this process becomes burdensome to the chairman, our board may elect to adopt more elaborate screening procedures.

### ***Code of Ethics***

Our board of directors has adopted a code of ethics which establishes the standards of ethical conduct applicable to all of our directors, officers, employees, consultants and contractors. The code of ethics addresses, among other things, competition and fair dealing, conflicts of interest, financial matters and external reporting, company funds and assets, confidentiality and corporate opportunity requirements and the process for reporting violations of the code of ethics, employee misconduct, conflicts of interest or other violations. Our code of ethics is publicly available on our website at <http://www.pmi2.com>. Any waiver of our code of ethics with respect to our chief executive officer, chief financial officer, controller or persons performing similar functions may only be authorized by our audit committee and will be disclosed as required by applicable law.

### ***Board of Directors' Recommendation***

Our Board of Directors recommends that you vote **FOR** the election of Charles W. Federico and David R. Murray as our Class I directors.

## PROPOSAL TWO—AMENDMENT TO OUR 2007 EQUITY INCENTIVE PLAN

### *Description of Amendment to Our 2007 Equity Incentive Plan*

On January 23, 2008, our board of directors approved an amendment to our 2007 Equity Incentive Plan (the “2007 Plan”) to increase the number of shares available for issuance under the plan by 945,164 shares, subject to shareholder approval at the 2008 Annual Meeting.

The purpose of the 2007 Plan is to further align the interests of our current and future directors, executive officers, employees, consultants and advisors with the interests of our stockholders by giving them an opportunity to acquire an ownership interest (or increase an existing ownership interest) in our company through the acquisition of shares of common stock. Stock options currently constitute a significant portion of the overall compensation of our key employees and our non-employee directors. The board of directors believes that the availability of an adequate reserve of shares for issuance under the 2007 Plan assists us in attracting and retaining key employees by enabling us to offer competitive compensation packages.

We are submitting Proposal Two for shareholder approval:

- to ensure that we will have a sufficient number of shares available under our 2007 Plan to enable us to attract and retain executive officers, outside directors and other key employees in a fashion that the board of directors believes is beneficial to our firm and its shareholders;
- to allow certain awards under our 2007 Plan to qualify as incentive stock options in accordance with Section 422 of the Internal Revenue Code;
- to allow certain awards under our 2007 Plan to be treated for federal income tax purposes as “qualified performance-based compensation,” which is excludable from the computation of the deduction limit set forth in Section 162(m) of the Internal Revenue Code; and
- to comply with the rules of The Nasdaq Stock Market, LLC.

As of April 14, 2008, 338,280 shares of common stock remain available for issuance pursuant to future awards under our 2007 Plan, without regard to the proposed amendment. The number of shares available for future awards could increase to the extent that shares underlying outstanding awards that have been issued under the 2007 Plan, or shares issued under our 2000 Stock Option Plan or 2004 Stock Incentive Plan, are forfeited, cancelled, reacquired, expire, are tendered in payment of the exercise price of options or otherwise terminate, for any reason (other than by exercise), but our 2007 Plan does not contain any other replenishment provision by which the number of shares available for issuance under the plan is automatically increased.

As of April 14, 2008, stock options to purchase an aggregate of 2,034,074 shares of our common stock were outstanding under our equity compensation plans. These options had a weighted average exercise price of approximately \$9.32 per share and a weighted average remaining term of 8 years. At April 14, 2008, restricted stock awards for an aggregate of 5,235 shares of our common stock were outstanding. We have no other equity-based compensation awards outstanding.

Prior to adopting the amendment to the 2007 Plan described above, our board of directors reviewed our historical grants of equity awards and management’s projections of the awards that we will likely issue under our 2007 Plan for compensating new hires and existing executive officers, outside directors, and other key employees in the upcoming years. Based on these projections, we believe it is likely that the pool of available shares remaining under our 2007 Plan will be exhausted before December 31, 2008. We believe that unless this pool of shares is increased, our ability to attract, retain, and motivate our management and other employees will be impaired.

Shareholder approval of the proposed increase to the maximum number of shares of our common stock issuable under our 2007 Plan would also have certain tax benefits to our employees. Our 2007

Plan allows us to award "incentive stock options," which receive favorable tax treatment under the Internal Revenue Code. The stock option grants under our 2007 Plan that are enabled by the proposed increase of the maximum number of shares available for issuance under the plan cannot qualify as incentive stock options unless the increase is approved by our shareholders.

Additionally, our 2007 Plan is specifically designed to preserve our ability to deduct the compensation we pay certain executive officers for income tax purposes. Section 162(m) of the Internal Revenue Code generally prevents us from deducting more than \$1.0 million in compensation each year for each of our five most highly compensated executive officers. Compensation treated as "qualified performance-based compensation" under Section 162(m) is not subject to this limitation. Awards granted under our 2007 Plan that are enabled by the proposed increase of the maximum number of shares available for issuance under the plan may be treated as "qualified performance-based compensation" only if the increase is approved by a majority vote of our shareholders.

Finally, as an issuer listed on the Nasdaq Global Select Market, we are required by the rules of The Nasdaq Stock Market, LLC to seek shareholder approval of any material amendment to any stock option or purchase plan or other equity compensation arrangement under which our executive officers, non-employee directors, or other employees may acquire shares of our common stock.

In order to pass, this proposal must receive a majority of the votes cast with respect to this matter.

#### ***Description of Our 2007 Equity Incentive Plan***

Our board of directors adopted our 2007 Plan in April 2007 and our stockholders approved it in May 2007. The 2007 Plan authorizes the issuance of awards for shares of our common stock to eligible individuals. The maximum number of shares initially authorized for issuance under our 2007 Plan was 2,434,985 shares, which was equal to the number of shares available for grant under our 2004 Stock Incentive Plan (discussed below) as of immediately prior to the completion of our initial public offering. As of April 14, 2008, there are approximately 714,535 shares subject to outstanding options to purchase common stock granted under the 2007 Plan.

The 2007 Plan is administered by the compensation committee of the board of directors. The compensation committee selects the individuals to whom awards will be granted and determines the exercise price and other terms of each award, subject to the provisions of the 2007 Plan.

The 2007 Plan authorizes the grant of options to purchase common stock intended to qualify as incentive stock options, as defined in Section 422 of the Internal Revenue Code, and non-statutory stock options.

Our officers, directors, employees, consultants and advisors are eligible to receive awards under the 2007 Plan. No participant may receive awards for over 625,000 shares of common stock in any calendar year.

Incentive options may be granted under the 2007 Plan to our employees and employees of our affiliates within the meaning of the Internal Revenue Code, including our officers and directors as well as officers and directors of our affiliates who are also employees. The exercise price of incentive options granted under the 2007 Plan must be at least equal to the fair market value of our common stock on the date of grant. The exercise price of incentive options granted to an optionee who owns stock possessing more than 10% of the voting power of our outstanding capital stock must be at least equal to 110% of the fair market value of the common stock on the date of grant. This type of optionee must exercise his or her option within five years from the date of grant.

Under the terms of the 2007 Plan, we may grant non-statutory options to our officers and other employees, our directors, and other individuals providing services to us.



The 2007 Plan provides that, upon a change of control of our company:

- each holder of an outstanding option, restricted stock award, performance share award or stock appreciation right shall be entitled, upon exercise of such option, to receive, in lieu of shares of our common stock, shares of such award or other securities, cash or property as the holders of our common stock received in connection with the change of control;
- the compensation committee may accelerate the time for exercise of all unexercised and unexpired options, restricted stock awards, performance share awards and stock appreciation rights; or
- all outstanding options, restricted stock awards, performance share awards and stock appreciation rights may be cancelled by the compensation committee as of the effective date of any such transaction, provided that notice of such cancellation shall be given to each holder of an award and that each holder of an award shall have the right to exercise such award to the extent that the same is then exercisable or, if the compensation committee shall have accelerated the time for exercise of all unexercised and unexpired options, restricted stock awards, performance share awards and stock appreciation rights, in full, during the 30-day period preceding the effective date of such a transaction.

For these purposes, a change of control means the occurrence of any of the following:

- any person becomes a beneficial owner of our securities representing 50% of the combined voting power of our then outstanding securities;
- we engage in a merger or consolidation under circumstances in which our stockholders immediately prior to such merger or consolidation do not own after such merger or consolidation shares representing at least 50% of the voting power of our company or the surviving or resulting corporation, as the case may be; or
- we approve a complete liquidation of, sell or otherwise dispose of, all or substantially all of our assets.

#### ***New Plan Benefits***

Because the grant of awards under the 2007 Plan will be made in the future at the discretion of the compensation committee of the board of directors, we are unable to determine the dollar value or number of shares or amounts that will be received by or allocated to any person, including any executive officer, director or employee, as a result of the increase in the number of shares subject to issuance under the 2007 Plan. If the proposed amendment had been in effect during 2007, it would not have affected the number of awards received by or allocated to participants in 2007.

#### ***Future Amendments to the 2007 Plan***

Our board of directors may, in its discretion, terminate or amend the 2007 Plan at any time, except that no such termination may affect options previously granted, nor may any amendment make a change in any award previously granted which would adversely affect the rights of an award holder under the 2007 Plan.

### *Other Equity Incentive Plans*

We currently have three other equity incentive plans under which awards have been or may be granted, as follows:

#### *2007 Employee Stock Purchase Plan*

Our board of directors adopted our 2007 Employee Stock Purchase Plan, or Purchase Plan, in April 2007 and our stockholders approved it in May 2007. A maximum of 75,000 shares of common stock are issuable under our Purchase Plan. No offering period has commenced and no options are outstanding under our Purchase Plan.

All of our employees who customarily work at least 20 hours per week and five months per year and who have completed 12 months of employment are eligible to participate our Purchase Plan. Employees who own stock and hold outstanding options to purchase stock representing 5% or more of the total combined voting power or value of all classes of our stock are not eligible to participate in the stock purchase plan.

At the commencement of each designated payroll deduction period, or offering period, an eligible employee may authorize us to deduct between 1% and 5%, in increments of 1%, of his or her base pay. On the last business day of the offering period, we will deem the employee to have exercised the option, at the exercise option price, to the extent of accumulated payroll deductions. The purchase price will be 85% of the closing market price of our common stock on the last day of the offering period, or the next trading day if the last day of the offering period is not a trading day. No employee is allowed to buy shares of common stock worth more than \$25,000, based on the fair market value of the common stock on the first day of the offering period, in any calendar year under the Purchase Plan. Our Purchase Plan is administered by the compensation committee of the board of directors.

#### *2004 Stock Incentive Plan*

In September 2004, we established our 2004 Stock Incentive Plan, which provided for the granting of restricted stock and of options which are intended to qualify either as incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or as options which are not intended to meet the requirements of such section. Options to purchase shares could be granted to persons who, in the case of incentive stock options, are our employees or, in the case of non-statutory stock options, are our employees, non-employee directors or consultants. At April 14, 2008, options to purchase an aggregate of 827,149 shares of our common stock granted under our 2004 Stock Incentive Plan were outstanding. We will no longer grant any new awards under our 2004 Stock Incentive Plan.

Generally, options granted under our 2004 Stock Incentive Plan vested over four years from the date of grant and expire ten years after the date granted. Options also terminated three months after the date on which employment is terminated, other than by reason of death or disability and one year from the date of termination due to death or disability, but in any event not later than the scheduled termination date.

#### *2000 Stock Option Plan*

In 2000, we established our 2000 Stock Option Plan, which provided for the granting of stock options which are intended to qualify either as incentive stock options within the meaning of Section 422 of the Internal Revenue Code of 1986, as amended, or as options which are not intended to meet the requirements of such section. Options to purchase shares could be granted to persons who, in the case of incentive stock options, are our employees or, in the case of non-statutory stock options, are our employees, non-employee directors or consultants. At April 14, 2008, options to purchase an

aggregate of 492,390 shares of our common stock granted under our 2000 Stock Option Plan were outstanding. We will no longer grant any new awards under our 2000 Stock Option Plan.

Generally, options granted under our 2000 Stock Option Plan vested over four years from the date of grant and expire ten years after the date granted. Options also terminated three months after the date on which employment is terminated, other than by reason of death or disability and one year from the date of termination due to death or disability, but in any event not later than the scheduled termination date.

***Board of Directors' Recommendation***

Our board of directors recommends that you vote FOR the proposal to approve the amendment to the 2007 Plan.

**PROPOSAL THREE—RATIFICATION OF APPOINTMENT OF INDEPENDENT  
REGISTERED PUBLIC ACCOUNTING FIRM**

Ernst & Young LLP currently serves as our independent registered public accounting firm and audited our consolidated financial statements for the year ended December 31, 2007. Our audit committee has appointed Ernst & Young LLP to serve as our independent registered public accounting firm for 2008 and to audit our consolidated financial statements for the year ending December 31, 2008.

Our audit committee is responsible for selecting and appointing our independent registered public accounting firm, and this appointment is not required to be ratified by our shareholders. However, our audit committee has recommended that the board of directors submit this matter to the shareholders as a matter of good corporate practice. If the shareholders fail to ratify the appointment, the audit committee will reconsider whether to retain Ernst & Young LLP, and may retain that firm or another without re-submitting the matter to our shareholders. Even if the appointment is ratified, the audit committee may, in its discretion, direct the appointment of a different independent registered public accounting firm at any time during the year if it determines that such a change would be in the best interests of our company and shareholders.

In order to pass, this proposal must receive a majority of the votes cast with respect to this matter.

***Board of Directors' Recommendation***

**Our board of directors recommends that you vote FOR the proposal to ratify the appointment of Ernst & Young LLP as our independent registered public accounting firm for 2008.**

## EXECUTIVE OFFICERS AND COMPENSATION OF EXECUTIVE OFFICERS

### *Executive Officers*

Alex T. Bourdon, our former chief operations officer, resigned from that position effective as of April 16, 2008. After Mr. Bourdon's resignation, we appointed Michael M. Fard as our vice president of operations. Mr. Fard, Donald Malinouskas, our vice president of research and development, and Keith Mintun, our vice president of sales and marketing, now report directly to Michael P. Whitman, our chief executive officer. Messrs. Whitman, Gandolfo, Fard, Malinouskas and Mintun are currently our only executive officers.

The following table sets forth information with respect to our executive officers as of April 14, 2008:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Michael P. Whitman . . . . .	47	President, Chief Executive Officer and Chairman of the Board of Directors
John P. Gandolfo . . . . .	47	Chief Financial Officer
Michael M. Fard . . . . .	48	Vice President, Operations
Donald Malinouskas . . . . .	62	Senior Vice President, Research and Development
Keith Mintun . . . . .	53	Senior Vice President, Sales

Further information regarding Michael P. Whitman is available under the section titled "Board of Directors—Directors Whose Term Extends Beyond the 2008 annual Meeting."

*John P. Gandolfo* has served as our Chief Financial Officer since January 2007. Prior to joining PMI, Mr. Gandolfo was the Chief Financial Officer of Bioject Medical Technologies, Inc., a publicly held supplier of needle-free drug delivery systems to the pharmaceutical and biotechnology industries, from September 2001 to May 2006. Prior to joining Bioject, Mr. Gandolfo was the Chief Financial Officer of Capital Access Network, Inc., a privately held specialty finance company, from 2000 through September 2001, and Xceed, Inc., a publicly held Internet consulting firm, from 1999 to 2000. From 1994 to 1999, Mr. Gandolfo was Chief Financial Officer and Chief Operating Officer of Impath, Inc., a publicly held, cancer-focused healthcare information company. A graduate of Rutgers University, Mr. Gandolfo is a certified public accountant (inactive status) who began his professional career at Price Waterhouse.

*Michael M. Fard* has been our Vice President, Operations since March 2008. From 1995 to 2007, Mr. Fard served as Vice President—New Product Development of MicroAire Surgical Instruments LLC, a provider of powered orthopedic surgical instruments. From 1992 to 1995, Mr. Fard was Vice President—Engineering and Operations of MicroAire. Before joining MicroAire, Mr. Fard held quality assurance management and engineering positions at Baxter International and American Hospital Supply. Mr. Fard received a B.S. in mechanical Engineering from California State University, Long Beach, and an M.B.A. from the College of William and Mary.

*Donald Malinouskas* has been our Senior Vice President of Research and Development since December 2007. Prior to joining PMI in March 2000, Mr. Malinouskas was a member of the technical staff at Spacelabs Medical where he was responsible for the advanced development of innovative new obstetrical measurement and wireless technologies. From 1984 to 1997, he was Chief Engineer at Advanced Medical Products. From 1978 to 1984, Mr. Malinouskas held various positions at United States Surgical Corporation, including Senior Project Manager, Project Manager and Principal Engineer. From 1973 to 1978, Mr. Malinouskas was at BD Electrodyne, a division of Becton Dickinson, where he served as section manager, principal engineer, Senior Design Engineer and Design Engineer. From 1970 to 1973, Mr. Malinouskas was a design engineer at Vanguard Medical Products where he worked on developing cardiac monitoring products. From 1968 to 1970, he was a Senior Field Representative at United Technologies where he was responsible for the installation and hospital staff

training for multi-channel telemetry cardiac monitoring systems. Mr. Malinouskas is a veteran of the United States Air Force.

*Keith Mintun* has been our Senior Vice President of Sales since March 2008. Prior to taking this position, Mr. Mintun served as our Vice President, Area Sales, since November 2000. Prior to joining PMI, Mr. Mintun held various positions in sales and marketing with Olympus America, including area Vice-President, Regional Sales Director, Regional Manager, and Sales Representative, from March 1988 to November 2000. From March 1978 to March 1988, Mr. Mintun held various sales positions with American Hospital Supply. Mr. Mintun received a Bachelor of Science Degree in Business and Public Administration from the University of Arizona.

## ***Compensation Discussion and Analysis***

### ***Overview***

This Compensation Discussion and Analysis discusses our policies and programs for compensating our executive officers and the compensation awarded to, earned by or paid to our executive officers in 2007. It provides information regarding the objectives and policies we apply in making compensation decisions and is accompanied by tabular disclosure and additional explanations of historical compensation paid to our named executive officers.

### ***Objectives of Our Compensation Policy***

We operate in an extremely competitive and rapidly changing industry. Our compensation committee believes that the compensation programs for the executive officers should be designed to attract, motivate and retain talented executives responsible for our success and should be determined within a framework that is intended to reward individual contribution and strong financial performance by our company. Within this overall philosophy, the compensation committee's objectives are to:

- offer a total compensation program that takes into consideration information available to us concerning the compensation practices of other companies with which we compete for executive talent;
- provide annual cash incentive awards that are based on our overall financial performance as well as individual contributions; and
- align the financial interests of executive officers with those of shareholders by providing significant long-term equity-based incentives.

Our compensation policy is designed to fairly reward our executives for their past efforts on our behalf and to encourage excellent performance in the future by affording them an opportunity to share in our success.

Our compensation committee also believes that the proportion of an individual's total compensation that is dependent on individual and company performance objectives should increase as that individual's business responsibilities increase.

### ***Role of Our Compensation Committee and Role of Our Executive Officers in the Compensation Process***

Our compensation committee makes recommendations to our board of directors concerning the compensation and benefits of our executive officers, which are considered and acted upon by our board of directors. Our board of directors has determined that each member of the compensation committee is independent within the meaning of the listing standards of The Nasdaq Stock Market, LLC, the rules of the Securities and Exchange Commission and the relevant securities laws, and that each member is an "outside director" as defined in Section 162(m) of the Internal Revenue Code of 1986, as amended. Before we established our compensation committee in October 2006, decisions regarding executive

compensation were made by our full board of directors based upon recommendations by our chief executive officer.

We obtain industry compensation data on an informal basis from publicly available surveys, from interviews with new and departing employees, and from anecdotal evidence obtained from members of our board of directors. We have not engaged the services of any compensation consultant or engaged in any systematic process of formal benchmarking of total compensation or any element of compensation of our executive officers.

The compensation committee has in the past typically considered recommendations made by Mr. Whitman regarding the performance, qualifications and proposed compensation for each executive officer, including himself. Mr. Whitman's recommendations encompass base salary, cash incentive awards and stock options. In 2007, the compensation committee approved, and the board of directors subsequently adopted, Mr. Whitman's recommendations for executive officer salaries, bonuses and equity incentive grants with only minor adjustments. Mr. Whitman, who is the chairman of our board of directors, has generally participated in deliberations and determinations of the board concerning compensation of our executive officers other than himself but has not participated in board deliberations or voted on matters relating to his own compensation.

#### *Elements of Compensation*

Executive compensation consists of the following:

##### Base salary

Our compensation committee establishes base salaries for our named executive officers based on their responsibilities, experience and expected contribution to our business. The compensation committee and Mr. Whitman also take into account anecdotal information available to us concerning the cash and equity compensation paid by similar companies with which we compete for executive talent. Our compensation committee reviews the base salaries of our executive officers annually taking into account each executive officer's effectiveness in achieving any corporate and personal goals set for the previous year, his or her expected contribution for the coming year and the competitive data. Base salaries are also evaluated relative to other components of our compensation program to ensure the executives' total compensation and mix of components is consistent with our compensation objectives and philosophies.

##### *2007 base salaries*

In 2006, we paid Mr. Whitman a base salary of \$320,000. In March 2007, we entered into an amended and restated employment agreement with Mr. Whitman that set his base salary at an annual rate of \$365,000. This represented an increase of 14% above his base salary rate in 2006. The compensation committee recommended the increase in Mr. Whitman's salary after extensive employment agreement negotiations between Mr. Whitman and the compensation committee between October 2006 and March 2007. In deciding whether to increase Mr. Whitman's base salary, the compensation committee considered the challenges of transforming PMI into a publicly held company and Mr. Whitman's expected contribution to our efforts to commercialize important new products currently under development.

In February 2007, we entered into an employment agreement with Mr. Gandolfo that set his base salary at \$250,000. Among other factors relevant to the determination of his base salary, the compensation committee considered Mr. Whitman's recommendation, Mr. Gandolfo's experience as a chief financial officer of publicly held companies and the challenge of becoming chief financial officer at a time of intense activity in the development of our business.

Mr. Bourdon's base salary of \$250,000 for 2007 was specified in his 2006 employment agreement.

### *2008 base salaries*

In December 2007, the compensation committee of our board of directors approved salary increases for 2008 for each of our named executive officers:

- we increased Mr. Whitman's base salary for 2008 to \$385,000, as required by his 2007 employment agreement;
- we increased Mr. Gandolfo's base salary for 2008 to \$275,000; and
- we increased Mr. Bourdon's base salary for 2008 to \$275,000.

Our employment agreements with Messrs. Whitman and Gandolfo are discussed below in the section titled "—Employment Agreements."

### Annual incentive bonus plan

Our annual incentive bonuses are intended to reward executives for assisting us to achieve our annual financial goals and for achieving individual performance objectives. These annual incentive bonuses are typically paid in cash within a few weeks after the end of each year. Financial goals for the company are determined by the board of directors at the beginning of each year and are subject to modifications by the board during the year. The individual annual performance objectives for Mr. Whitman are determined by the compensation committee after negotiations with Mr. Whitman. The annual performance objectives for Messrs. Bourdon and Gandolfo are determined by the compensation committee after considering recommendations from Mr. Whitman. Target bonuses, usually expressed as a percentage of base salary, are also determined at the beginning of each year. The target bonuses for Messrs. Bourdon and Gandolfo for 2007, determined as set forth in their employment contracts, were fixed at 35%. The target bonuses for Mr. Whitman for 2007 were set forth in his amended and restated employment agreement. The determinations as to whether we or the individual have achieved their respective goals, and the amounts of the annual incentive bonuses actually payable at the end of the year, are made by the compensation committee after considering recommendations from Mr. Whitman, including as to himself.

### *2007 short-term cash incentive awards*

In December 2007, the compensation committee of our board of directors approved cash bonuses for 2007 for each of our executive officers:

- we awarded Mr. Whitman a cash bonus of \$54,750 for the successful launch of our i60 product in 2007, as required by his 2007 employment agreement;
- we awarded Mr. Whitman an additional discretionary cash bonus of \$72,500 for his services in 2007, largely in recognition of the completion of our initial public offering in October 2007;
- we awarded Mr. Gandolfo a discretionary cash bonus of \$37,275 for his services in 2007; and
- we awarded Mr. Bourdon a discretionary cash bonus of \$26,250 for his services in 2007.

Mr. Whitman was eligible, under his 2007 employment agreement, to receive a cash bonus of up to \$550,000 for 2007, based upon the achievement of company performance objectives that were approved by our compensation committee. These objectives included the consummation of a qualified public offering of our common stock in 2007, achievement of revenue, net income (loss) and gross margin targets for 2007, and successful market launch of our new i60 product in 2007. Although the specific conditions for the completion of a qualified initial public offering under Mr. Whitman's employment agreement were not met, in December 2007, our compensation committee awarded Mr. Whitman a discretionary cash bonus of \$72,500 largely in recognition of the completion of our initial public offering in October 2007. A cash bonus of \$54,750 was awarded to Mr. Whitman in December 2007 for the successful market launch of our i60 product in 2007, as required by Mr. Whitman's employment



agreement. Our compensation committee concluded that the other performance objectives in Mr. Whitman's employment agreement were not met in 2007.

Mr. Gandolfo was eligible, under his 2007 employment agreement, to receive a cash bonus for 2007 of up to 35% of his base salary, based upon the achievement of company and individual performance objectives approved by Mr. Whitman and the compensation committee. These objectives included the completion of our convertible note financing, the consummation of an initial public offering meeting certain criteria, achievement of revenue, net income (loss) and gross margin targets for 2007 and implementation of specified compliance and investor relations programs during 2007. The cash bonus we paid to Mr. Gandolfo for 2007 amounted to 15% of his base salary for 2007, and was awarded primarily in recognition of the successful completion of our convertible note financing in March 2007 and our initial public offering in October 2007.

Mr. Bourdon was eligible, under his 2006 employment agreement, to receive a cash bonus for 2007 in an amount of up to 35% to 100% of his base salary, based upon the achievement of company and individual performance objectives approved by Mr. Whitman and the compensation committee. These objectives included the achievement of revenue, net income (loss) and gross margin targets for 2007 and implementation of specified operational objectives, including market launches of our new i60 and iNOLC, or natural orifice linear cutter, products, bringing our new automated reload assembly system on line, implementation of improved inventory and cost management systems and achievement of regulatory compliance and ISO certification objectives. The cash bonus we paid to Mr. Bourdon for 2007 amounted to 11% of his base salary for 2007, and was awarded primarily in recognition of the market launch of our i60 product in 2007.

#### *2008 short-term cash incentive plans*

In February 2008, our compensation committee approved short-term cash incentive plans for Messrs. Whitman, Gandolfo and Bourdon for 2008, as required by their employment agreements. All three cash incentive plans provide that if we achieve a specified revenue target and do not exceed a specified operating loss target in fiscal year 2008, and if these officers remain employed by us throughout the year, then we will pay them cash bonuses in early 2009. Effective April 16, 2008, Mr. Bourdon will no longer be employed by us, and will not be eligible to receive a cash bonus for 2008.

The cash bonus to be paid to Mr. Gandolfo for fiscal year 2008 will equal the lesser of (x) \$275,000 or (y) the sum of (A) \$96,250 plus (B) 29.4% of a "Savings Bonus Pool." The cash bonus for Mr. Whitman for fiscal 2008 will equal the lesser of (x) \$577,500 or (y) the sum of (A) \$288,750 plus (B) 41.2% of the Savings Bonus Pool. The "Savings Bonus Pool" will be 30% of the amount, if any, by which our actual operating loss in fiscal year 2008 is more favorable (i.e., less than) the specified operating loss objective.

The revenue and operating loss targets for 2008 established for purposes of the 2008 bonus plans for Messrs. Whitman and Gandolfo are based upon the operating plan for 2008 approved by our board of directors on January 23, 2008. The targets are aspirational in nature, and require results more favorable than stated in the board approved operating plan for 2008. We believe the achievement of these financial performance targets is not assured, and presents our executive officers with a significant challenge. The financial performance targets established for our executive officers' short-term cash incentive plans for 2007, which were intended to present a similar challenge, were not achieved.

#### Long-term equity incentive program

To date, all of the long-term equity incentives granted to our executive officers have been in the form of non-statutory options to purchase common stock, which we believe provide an effective incentive with respect to future performance and an effective retention mechanism as a result of the applicable vesting mechanics of the awards.

Our board of directors awards stock options to our executive officers based upon recommendations from our compensation committee. In formulating its recommendations, the compensation committee considers recommendations from Mr. Whitman. In determining the number of shares to be included in each option, the compensation committee considers the executive's responsibilities, expected future contribution to our operating results and equity compensation paid by other companies to similarly situated executive officers. The exercise prices of our stock option grants are set at or above the fair market value of a share of our stock at the time of the grant.

The board of directors grants options for new hires at regularly scheduled board meetings and with exceptions described below, generally grants additional options, if any, to current employees once per year in connection with their annual performance evaluations, generally in December.

#### *2007 equity incentive awards*

In April 2007, our board of directors granted Mr. Whitman a non-statutory option to purchase 380,068 shares of our common stock at an exercise price of \$10.24 per share, in connection with the execution of his amended and restated employment agreement. This option is performance-based and vests only upon the achievement of corporate performance targets beginning in 2007. Specifically, 25% of the shares were scheduled to vest upon the completion of our initial public offering, 25% were scheduled to vest upon the successful launch of the i60 product in 2007, 40% were scheduled to vest upon achievement of an annual revenue target for 2007, and the remaining 10% were scheduled to vest upon achievement of a net income (loss) target for 2007. Additionally, all of the shares would vest upon a change in control of the company, as defined in Mr. Whitman's employment agreement, occurring in 2007. The performance objectives other than the launch of our i60 product were not met in 2007, and accordingly, only 95,017 shares vested under Mr. Whitman's 2007 performance-based option.

In April 2007, our board of directors granted Mr. Gandolfo a non-statutory option to purchase 114,418 shares of our common stock, at an exercise price of \$10.24 per share, in connection with the execution of his amended and restated employment agreement.

#### *2008 equity incentive awards*

In December 2007, our compensation committee awarded non-qualified options to purchase shares of our common stock to Mr. Gandolfo and Mr. Bourdon under our 2007 Equity Incentive Plan, as follows: Mr. Gandolfo, 14,890 shares and Mr. Bourdon, 20,340 shares. The exercise price for each stock option is \$14.25 per share, which was the last reported sale price of our common stock on the NASDAQ Global Market on the date of grant. The stock options vest as to 25% of the shares on the first anniversary of the date of grant and as to an additional 6.25% of the total shares at the end of each successive three-month period following the first anniversary of the date of grant until the fourth anniversary of the date of grant. The December 2007 option awarded to Mr. Gandolfo was primarily in recognition of the successful completion of our initial public offering in October 2007. The December 2007 option awarded to Mr. Bourdon was primarily in recognition of additional responsibilities accepted by Mr. Bourdon.

In January 2008, our compensation committee granted Mr. Whitman a non-qualified option to purchase 413,768 shares of our common stock. The timing of this grant and the number of shares purchasable under the option were prescribed in Mr. Whitman's 2007 employment agreement. The option was granted under our 2007 Equity Incentive Plan and has an exercise price of \$11.31 per share, which was the last reported sale price of our common stock on the NASDAQ Global Market on the date of grant. The option vests over 4 years in equal quarterly installments, with the first installment vesting on March 31, 2008.

### Severance and change of control benefits

Messrs. Whitman and Gandolfo are entitled to receive severance benefits upon certain qualifying terminations of employment based on applicable provisions in their respective employment agreements. These severance arrangements are intended to assist us in attracting and retaining qualified executives and provide for continuity of management in connection with a threatened or actual change in control transaction.

Under Mr. Whitman's amended and restated employment agreement, if we terminate his employment without cause (as defined in his employment agreement) or he terminates his employment due to a breach by us, then he would be entitled to receive his base salary and benefits until December 31, 2008, all shares purchasable under any option granted in 2008, would become vested and he would be entitled to receive any guaranteed bonus (not performance-based). If we do not extend Mr. Whitman's employment agreement beyond 2008, then we will be required to pay him a severance payment equal to 150% of his base salary as of December 31, 2008. In the event of a change of control (as defined in his employment agreement), we will be required to pay Mr. Whitman a severance payment equal to 150% of his base salary as of the closing of such transaction and all of the shares purchasable under his outstanding stock options will become vested.

Under Mr. Gandolfo's employment agreement, if we terminate his employment without cause prior to a change of control (each as defined in his employment agreement), he will be entitled to receive his base salary for six months after the date of termination. If we terminate his employment without cause after a change of control, he will be entitled to receive his base salary for one year after the date of termination. Also, if a change of control occurs prior to the first anniversary of the date of Mr. Gandolfo's employment agreement, then 50% of the shares purchasable under his April 2007 stock option will become vested, and if a change of control occurs after the first anniversary of the date of his employment agreement, then all of the shares purchasable under his April 2007 and December 2007 stock options will become vested.

### Perquisites and other compensation

We also provide other benefits to certain of our executive officers that are not tied to any formal individual or company performance criteria and are intended to be part of a competitive overall compensation program. For 2007, these benefits included payment of term life insurance premiums, certain automobile and cell phone expenses, payment of premiums for disability insurance, and in the case of Mr. Whitman, we compensate Mr. Whitman up to \$10,000 annually to cover income taxes owed in connection with the previously mentioned perquisites. See "—Summary Compensation Table."

### Employment Agreements

*Michael P. Whitman.* On March 23, 2007 we entered into a second amended and restated employment agreement with Michael P. Whitman, pursuant to which he has agreed to serve as our chief executive officer through December 31, 2008. The agreement provides for a minimum base salary of \$365,000 for 2007 and \$385,000 for 2008. Pursuant to this employment agreement, Mr. Whitman is eligible to receive cash bonuses based upon the achievement of certain company performance objectives that are approved by our compensation committee. The agreement also required that we grant Mr. Whitman in January 2008 a non-qualified stock option to purchase a specified number of shares of our common stock. Mr. Whitman's employment agreement was amended on February 4, 2008 to provide specific performance targets set by our compensation committee upon which Mr. Whitman's 2008 cash bonus will be determined and paid.

Under Mr. Whitman's amended and restated employment agreement, if we terminate his employment without cause (as defined in his employment agreement) or he terminates his employment due to a breach by the company, if we do not extend Mr. Whitman's employment agreement beyond 2008, or if a change of control (as defined in his employment agreement) occurs, then he will be entitled to certain severance payments and other benefits described above.

*John P. Gandolfo.* We have entered into an employment agreement dated January 5, 2007, with John P. Gandolfo, pursuant to which he has agreed to serve as our chief financial officer through December 31, 2009. The agreement provides for an initial base salary of \$250,000, which will be reviewed annually by our chief executive officer and can be increased at the beginning of each calendar year. He is eligible to receive an annual bonus with a target bonus of 35% of base salary, based upon the achievement of certain company and individual performance objectives approved by our chief executive officer and the compensation committee of our board of directors. Mr. Gandolfo's employment agreement was amended on February 4, 2008 to provide specific performance targets set by our compensation committee upon which Mr. Gandolfo's 2008 cash bonus will be determined and paid. If we terminate Mr. Gandolfo without cause (as defined in his employment agreement), or if a change of control occurs, then he will be entitled to certain severance payments and other benefits described above. Under the employment agreement, Mr. Gandolfo is subject to customary non-solicitation, non-competition and confidentiality covenants.

#### *401(k) Plan*

We maintain a defined contribution employee retirement plan, or 401(k) plan, for our employees. Our executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to qualify as a tax-qualified plan under Section 401(k) of the Internal Revenue Code. The plan provides that each participant may contribute up to 15% of his or her pre-tax compensation, up to the statutory limit, which is \$15,500 for calendar year 2008. Participants who are 50 years or older can also make catch-up contributions, which in calendar year 2008 may be up to an additional \$5,000 above the statutory limit. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions, including any matching contributions by us, when contributed. Participant contributions are held and invested by the plan's trustee. The plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. In 2007, we did not match participant contributions.

## Compensation of Our Executive Officers

### Summary Compensation Table

The following table provides information regarding the compensation earned during the years ended December 31, 2006 and 2007 by our chief executive officer and each other person who served as an executive officer during 2007, was in office on December 31, 2007 and whose total compensation exceeded \$100,000 for the year ended December 31, 2007. We refer to these officers as our named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards (\$)(1)	All Other Compensation (\$)(2)	Total (\$)
Michael P. Whitman	2007	365,000	127,250(3)	423,548(4)	69,915(5)	985,713
President, Chief Executive Officer and Chairman	2006	320,000	115,000	80,626	37,216(6)	552,842
John P. Gandolfo(7)	2007	246,153	37,275	631,386	4,385(8)	919,199
Chief Financial Officer						
Alex T. Bourdon(9)	2007	250,000	26,250	165,769	4,385(8)	446,404
Former Chief Operations Officer	2006	33,654	—	—	—	33,654

- (1) Amounts shown do not reflect compensation actually received by the named executive officer. The amounts shown represent expense recognized in our 2007 and 2006 consolidated financial statements in accordance with SFAS 123(R), except that we have disregarded any estimate of future forfeitures related to service-based vesting conditions with respect to such option awards. Options to purchase 114,481 shares of our common stock will be forfeited by Mr. Bourdon if not exercised prior to his departure on April 16, 2008. The other assumptions used to calculate the expense amounts shown for stock options granted in 2006 and 2007 are set forth in Note 2 to the consolidated financial statements in our annual report on Form 10-K for the year ended December 31, 2007.
- (2) Except as described in the following footnotes, our named executive officers did not receive or earn any other perquisites, personal benefits or property as compensation for their services in 2006 or 2007. Reported compensation is valued on the basis of its aggregate incremental cost to us.
- (3) Consists of a discretionary cash bonus of \$72,500 for Mr. Whitman's services in 2007, and a cash bonus of \$54,750 in connection with the successful market launch of our new i60 product in 2007, as required by Mr. Whitman's employment agreement.
- (4) Represents the compensation expense related to the vesting of 25% of the performance-based option granted to Mr. Whitman on April 2007. Mr. Whitman vested in 95,017 shares in connection with the successful launch of our i60 product in 2007. The remaining 75% of the option did not, and will not, vest because the conditions for vesting, other than the successful launch of the i60 product, were not met in 2007. For more information concerning Mr. Whitman's 2007 equity incentive awards, see the section titled "2007 equity incentive awards" above.
- (5) Consists of premiums paid for life insurance in the amount of \$3,325, an automobile allowance and cell phone allowance in the amount of \$22,645, legal fees paid on Mr. Whitman's behalf to cover contract negotiation services in the amount of \$28,351 and amounts paid to Mr. Whitman to cover a portion of the income taxes owed for these benefits in the amount of \$15,594.
- (6) Consists of premiums paid for life insurance in the amount of \$3,325, an automobile allowance and cell phone allowance in the amount of \$18,000, and amounts paid to Mr. Whitman to cover a portion of the income taxes owed for these benefits in the amount of \$15,891.

- (7) Mr. Gandolfo was appointed as our chief financial officer on January 5, 2007.
- (8) Amount represents automobile allowance.
- (9) Mr. Bourdon became our chief operations officer on October 27, 2006 and resigned from that position on March 17, 2008, effective as of April 16, 2008.

*Grants of Plan-Based Awards*

The following table sets forth information regarding all plan-based awards to our named executive officers during 2007.

<u>Name and Principal Position</u>	<u>Grant Date</u>	<u>All Other Option Awards: Number of Securities Underlying Options (#)</u>	<u>Exercise or Base Price of Option Awards (\$/Sh)(1)</u>	<u>Grant Date Fair Value of Stock Option Awards(2)</u>
Michael P. Whitman President, Chief Executive Officer and Chairman	04/18/07	380,068	10.24	\$1,694,191(3)
John P. Gandolfo Chief Financial Officer	04/18/07 12/14/07	114,419 14,890	10.24 14.25	\$ 510,034 \$ 121,352
Alex T. Bourdon Former Chief Operations Officer	12/14/07	20,340	14.25	\$ 165,769(4)

- (1) The exercise price of each option was not less than the per share fair market value of our common stock, as determined in good faith by our board of directors on the grant date. Since the closing of our initial public offering in October 2007, we have utilized the quoted market price on the date of grant as the fair market value of our common stock within our Black-Scholes option pricing model.
- (2) Amount reflects the total fair value of stock options awarded in 2007 as of the date of grant, calculated in accordance with SFAS No. 123(R).
- (3) This option was performance-based and vested only upon the achievement of corporate performance targets beginning in 2007. Specifically, 25% of the shares were scheduled to vest upon the completion of our initial public offering offering, 25% were scheduled to vest upon the successful launch of the i60 product in 2007, 40% were scheduled to vest upon achievement of an annual revenue target for 2007, and the remaining 10% were scheduled to vest upon achievement of a net income (loss) target for 2007. Additionally, all of the shares would vest upon a change in control of the company, as defined in Mr. Whitman's employment agreement, occurring in 2007. The performance objectives other than the launch of our i60 product were not met in 2007. Accordingly, only 95,017 shares vested under Mr. Whitman's 2007 performance-based option during 2007 and no further vesting will occur under the option.
- (4) No portion of this option will vest, as a result of Mr. Bourdon's resignation from our employment.

### *Outstanding Equity Awards at Fiscal Year-End*

The following table sets forth information regarding all outstanding equity awards held by our named executive officers at December 31, 2007.

Name and Principal Position	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Michael P. Whitman	210,875	—	4.48	10/15/2013
President, Chief Executive Officer and Chairman	4,688	—	6.40	2/1/2015
	49,230	16,409	6.40	6/1/2015
	54,147	54,147	6.40	12/1/2015
	43,639	72,736	10.24	6/1/2016
	95,017	285,051	10.24	4/18/2017
John P. Gandolfo	—	114,419	10.24	4/18/2017
Chief Financial Officer	—	14,890	14.25	12/14/2017
Alex T. Bourdon(1)	37,656	112,969	10.24	11/13/2016
Former Chief Operations Officer	—	20,340	14.25	12/14/2017

- (1) Mr. Bourdon resigned as our chief operations officer on March 17, 2008, effective April 16, 2008. No portion of the option for 20,340 shares issued to Mr. Bourdon on December 14, 2007 will vest. All outstanding stock options held by him will expire on July 15, 2008 if not exercised before that date.

### *Option Exercises and Stock Vested for 2007*

Our named executive officers did not exercise any stock options or hold any restricted stock, restricted stock unit or other similar equity-based award during the year ended December 31, 2007.

### *Pension Benefits for 2007*

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2007.

### *Nonqualified Deferred Compensation for 2007*

Our named executive officers did not earn any nonqualified deferred compensation from us during the year ended December 31, 2007.

### *Equity Compensation Plan Information*

We have two equity compensation plans under which shares are currently authorized for issuance, our 2007 Plan and our 2007 Employee Stock Purchase Plan. In addition, we have two equity compensation plans under which awards are currently outstanding but pursuant to which no future awards may be granted, our 2000 Plan and our 2004 Plan. All of our equity compensation plans were approved by our stockholders prior to our initial public offering in October 2007. The following table

provides information regarding securities authorized for issuance as of December 31, 2007 under our equity compensation plans.

<u>Plan Category</u>	<u>Number of shares to be issued upon exercise of outstanding options, warrants and rights(1) (a)</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights (b)</u>	<u>Number of shares remaining available for future issuance under equity compensation plans (excluding shares reflected in column (a)) (c)</u>
Equity Compensation Plans Approved by Security Holders	1,728,844	\$9.08	643,510
Equity Compensation Plans Not Approved by Security Holders	<u>—</u>	<u>—</u>	<u>—</u>
Total	<u>1,728,844</u>	<u>\$9.08</u>	<u>643,510</u>

(1) Excludes 5,235 shares outstanding as of December 31, 2007 in the form of restricted stock awards issued under our 2007 Plan, which were issued without the payment of any consideration by the recipients.

#### ***Compensation Committee Report***

The compensation committee of our board of directors hereby reports as follows:

1. The compensation committee has reviewed and discussed the Compensation Discussion and Analysis section contained in this proxy statement.
2. Based on the review and discussion referred to in paragraph (1) above, the compensation committee recommended to our board of directors that the Compensation Discussion and Analysis be included in this proxy statement and incorporated by reference in the Annual Report on Form 10-K for the fiscal year ended December 31, 2007 filed with the Securities and Exchange Commission.

The foregoing report is provided by the undersigned members of the compensation committee.

David R. Murray, *Chair*  
Gerald Dorros, M.D.  
Lon E. Otremba

*The foregoing Compensation Committee Report shall not be deemed to be soliciting material or filed or incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended and shall not otherwise be deemed filed under these acts, except to the extent we specifically incorporate it by reference into such filings.*



## INFORMATION ABOUT COMMON STOCK OWNERSHIP AND PERFORMANCE

### *Stock Owned by Directors, Executive Officers and Greater-Than-5% Stockholders*

The following table sets forth certain information with respect to beneficial ownership of our common stock, as of April 14, 2008, by:

- each beneficial owner of 5% or more of the outstanding shares of our common stock;
- each of our named executive officers and other executive officers;
- each of our directors and nominees for election as director; and
- all of our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of common stock subject to options, warrants or convertible promissory notes held by that person that are currently exercisable or convertible, or exercisable within 60 days of April 14, 2008 are deemed outstanding, but are not deemed outstanding for computing the percentage ownership of any other person. To our knowledge, except as set forth in the footnotes to this table and subject to applicable community property laws, each person named in the table has sole voting and investment power with respect to the shares set forth opposite such person's name. Except as otherwise indicated, the address of each of the persons in this table is c/o Power Medical Interventions, Inc., 2021 Cabot Boulevard, Langhorne, Pennsylvania 19047.

Each stockholder's percentage ownership before the offering is determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended, and is based on 17,108,102 shares of our common stock outstanding as of April 14, 2008. As of April 14, 2008, our outstanding convertible notes are convertible in accordance with their terms into an aggregate of 2.6 million shares of our common stock. Except as set forth above, the table below assumes no conversion of these notes, and no exercise of stock options and warrants outstanding at April 14, 2008 to purchase an aggregate of approximately 2.4 million shares of our common stock. Amounts under the heading "Right to

Acquire” represent shares that may be acquired upon exercise of stock options or warrants exercisable within 60 days of the date of the table or upon conversion of our convertible promissory notes.

Name and Address of Beneficial Owner	Beneficial Ownership			
	Shares Outstanding	Right to Acquire	Total	% of Outstanding
<i>5% Stockholders</i>				
Boston Scientific Corporation . . . . . One Boston Scientific Place Natick, Massachusetts 01760	2,205,417	9,060	2,214,477	12.9%
Gerald and Myra S. Dorros Revocable Trust(1) . . .	1,892,008	321,098	2,213,106	12.7%
Entities affiliated with Davidson Kempner Partners(2) . 885 Third Avenue New York, New York 10022	1,500,000	—	1,500,000	8.8%
Entities affiliated with NGN Capital LLC . . . . . 369 Lexington Avenue New York, New York 10017	1,151,047	5,078	1,156,125	6.8%
<i>Executive Officers and Directors</i>				
Gerald Dorros, M.D.(3) . . . . .	1,892,008	321,098	2,213,106	12.7%
Kenneth S. Abramowitz(4) . . . . .	1,151,047	5,078	1,156,125	6.8%
Michael P. Whitman . . . . .	253,123	515,642	768,765	4.4%
John C. Moran(5) . . . . .	33,994	15,088	49,082	*
Alex T. Bourdon . . . . .	—	56,484	56,484	*
Keith Mintun . . . . .	200	46,875	47,075	*
Donald Malinouskas . . . . .	—	44,933	44,933	*
John P. Gandolfo . . . . .	—	38,139	38,139	*
James R. Locher III . . . . .	4,687	16,031	20,718	*
David R. Murray . . . . .	—	781	781	*
Lon E. Otremba . . . . .	—	781	781	*
Charles W. Federico(6) . . . . .	—	—	—	*
Michael M. Fard . . . . .	—	—	—	*
All current directors and executive officers as a group (12 persons) . . . . .	3,335,059	1,060,930	4,395,989	24.2%

\* Less than 1.0%

(1) Includes securities owned by Gerald Dorros, M.D.

(2) Based solely upon the Schedule 13G/A of Davidson Kempner Partners filed with the SEC on February 14, 2008, with respect to common stock owned as of that date.

(3) Includes securities owned by the Gerald and Myra S. Dorros Revocable Trust. Dr. Dorros disclaims beneficial ownership of the shares held by the Gerald and Myra S. Dorros Revocable Trust except to the extent of his pecuniary interest therein.

(4) Shares presented in the Shares Outstanding column include (i) 668,091 shares held by NGN BioMed Opportunity I, L.P. and (ii) 482,996 shares held by NGN BioMed Opportunity I GmbH&Co. Beteiligungs KG. Shares included in the Right to Acquire column include 4,297 shares issuable upon exercise of a stock option held by NGN Capital LLC. Mr. Abramowitz is managing general partner of NGN Capital LLC. Mr. Abramowitz disclaims beneficial ownership of the shares held by NGN Capital LLC and its affiliates, except to the extent of his pecuniary interest.

- (5) Includes 7,513 shares of common stock held by Robin Hood Ventures 10, LP and 17,877 shares of common stock held by Robin Hood Ventures 10A, LP. Mr. Moran is a limited partner of both Robin Hood Ventures 10, LP and Robin Hood Ventures 10A, LP. The Right to Acquire column includes 2,681 shares issuable upon exercise of a common stock purchase warrant held by Robin Hood Ventures 10A, LP. Mr. Moran disclaims beneficial ownership of the securities held by Robin Hood Ventures 10, LP and Robin Hood Ventures 10A, LP.
- (6) Mr. Federico is a nominee for election as a Class I director.

***Section 16(a) Beneficial Ownership Reporting Compliance***

Section 16(a) of the Securities Exchange Act of 1934 requires our directors and executive officers, and persons who beneficially own more than ten percent of a registered class of our equity securities, to file reports of ownership of, and transactions in, our securities with the Securities and Exchange Commission. These directors, executive officers and ten-percent shareholders are also required to furnish us with copies of all Section 16(a) forms they file.

Based solely on a review of the copies of such forms received by us, and on written representations from certain reporting persons, we believe that during 2007 our directors, officers and ten-percent shareholders complied with all applicable Section 16(a) filing requirements, with the exceptions noted below.

Alex T. Bourdon, our former chief operations officer, and John P. Gandolfo, our chief financial officer, were each late in filing a Form 4 to report the receipt of stock options granted by our board of directors in December 2007.

Messrs. Abramowitz, Dorros, Locher, Moran and Otremba, each a non-employee director, each filed a Form 5 reporting the receipt of stock options granted by our board of directors in December 2007 that should have been reported on an earlier Form 4.

## INFORMATION ABOUT OUR AUDIT COMMITTEE AND AUDITORS

### *Our Auditors*

Ernst & Young LLP have been selected by the audit committee of the board of directors as the independent registered public accounting firm to audit our financial statements for the year ending December 31, 2008. Ernst & Young LLP also served as our auditors in 2007. We expect that representatives of Ernst & Young LLP will attend our annual meeting, will have an opportunity to make a statement if they desire to do so, and will be available to respond to appropriate questions.

### *Audit Committee Report*

The primary role of our audit committee is to assist our board of directors in fulfilling its oversight responsibilities by reviewing the financial information proposed to be provided to shareholders and others, the adequacy of the system of internal control over financial reporting and disclosure controls and procedures established by management and the board, and the audit process and the independent auditors' qualifications, independence and performance.

Management is responsible for establishing and maintaining our system of internal controls and for preparation of our financial statements. Our independent registered public accounting firm, Ernst & Young LLP, is responsible for performing an audit of our consolidated financial statements in accordance with generally accepted auditing standards and issuing an opinion on the financial statements. The audit committee has met and held discussions with management and our independent auditors, and has also met separately with our independent auditors, without management present, to review the adequacy of our internal controls, financial reporting practices and audit process.

The audit committee has reviewed and discussed our audited consolidated financial statements for the year ended December 31, 2007. As part of this review, the audit committee discussed with Ernst & Young LLP the communications required by generally accepted auditing standards, including those described in Statement on Auditing Standards No. 61, "Communication with Audit Committees."

The audit committee has received from Ernst & Young LLP a written statement describing all relationships between that firm and the Company that might bear on the auditors' independence, consistent with Independence Standards Board Standard No. 1, "*Independence Discussions with Audit Committees*." The audit committee has discussed the written statement with the independent auditors, and has considered whether the independent auditors' provision of any consultation and other non-audit services to the Company is compatible with maintaining the auditors' independence.

Based on the above-mentioned reviews and discussions with management and the independent auditors, the audit committee recommended to the board of directors that the Company's audited consolidated financial statements be included in its Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission.

The foregoing report is provided by the undersigned members of the audit committee.

John C. Moran, *Chair*  
Kenneth S. Abramowitz  
Lon E. Otremba

*The foregoing audit committee report shall not be deemed to be soliciting material or filed or incorporated by reference into any filing under the Securities Act of 1933, or the Securities Exchange Act of 1934, as amended, and shall not otherwise be deemed filed under these acts, except to the extent we specifically incorporate it by reference into such filings.*

### ***Fees for Professional Services***

The following is a summary of the fees for professional services rendered by Ernst & Young LLP for 2007 and 2006:

Fee category	Fees	
	2007	2006
Audit fees . . . . .	\$1,895,000	\$335,000
Audit-related fees . . . . .	18,000	18,000
Tax fees . . . . .	29,000	23,000
All other fees . . . . .	—	—
Total Fees . . . . .	<u>\$1,942,000</u>	<u>\$376,000</u>

*Audit fees.* Audit fees represent fees for professional services performed by Ernst & Young LLP for the audit of our annual financial statements and the review of our quarterly financial statements, as well as services that are normally provided in connection with statutory and regulatory filings or engagements and related expenses. The fee of \$1,895,000 disclosed for 2007 above includes \$1,590,000 related to services in connection with our initial public offering in 2007.

*Audit-related fees.* Audit-related fees represent fees for assurance and related services performed by Ernst & Young LLP that are reasonably related to the performance of the audit or review of our financial statements, including consultation on accounting standards or accounting for specific transactions.

*Tax fees.* Tax fees represent fees for professional services performed by Ernst & Young LLP with respect to tax compliance, tax advice and tax planning and related expenses. These services include assistance with the preparation of federal, state, and foreign income tax returns.

*All other fees.* All other fees represent fees for products and services provided by Ernst & Young LLP, other than those disclosed above.

### ***Pre-Approval Policies and Procedures***

Our audit committee approves each engagement for audit or non-audit services before we engage Ernst & Young LLP to provide those services. All audit and non-audit services require specific pre-approval by the audit committee.

Our audit committee's pre-approval policies or procedures do not allow our management to engage Ernst & Young LLP to provide any specified services without audit committee pre-approval of the engagement for those services. All of the services provided by Ernst & Young LLP during 2007 were individually pre-approved on a case by case basis.

### ***Whistleblower Procedures***

Our audit committee has adopted procedures for the treatment of complaints regarding accounting, internal accounting controls or auditing matters, including procedures for the confidential and anonymous submission by our directors, officers and employees of concerns regarding questionable accounting, internal accounting controls or auditing matters. These procedures are set forth in our code of ethics. See "Election of Class I Directors—Code of Ethics."

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

### *Policies and Procedures*

Pursuant to an unwritten policy of the board of directors, we submit all transactions involving a commitment greater than a stated amount, which currently is \$500,000, that we contemplate entering into, including related person transactions, to the board of directors for approval. In addition, we have adopted a written policy providing that our audit committee is responsible for reviewing and approving all transactions between us and any related person which are of a character that would require disclosure under Item 404 of Regulation S-K. Our policy provides that a "related person transaction" is any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, involving an amount exceeding \$120,000 in which we are a participant and in which any of our executive officers, directors or 5% stockholders, or any immediate family member of any of our executive officers, directors or 5% stockholders, has or will have a direct or indirect material interest. Pursuant to our policy, neither our audit committee nor our board of directors will approve or ratify any related person transaction which the audit committee or the board of directors, as the case may be, determines is not in, or not inconsistent with, the best interests of the Company. Each of the related party transactions listed below was approved by a disinterested majority of our board of directors after full disclosure of the interest of the related party in the transaction.

In addition to the compensation arrangements with directors and the executive officers described above, the following is a description of each transaction during fiscal year 2007 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeds \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of or person sharing the household with any of these individuals, had or will have a direct or indirect material interest.

### *Transactions with Gerald Dorros, M.D.*

Gerald Dorros, M.D. is a co-founder and director of the Company and is one of our largest stockholders, owning beneficially approximately 12.7% of our outstanding common stock. We entered into the following transactions with Dr. Dorros during fiscal 2007 and 2008 to date.

*Amendments to common stock purchase warrants.* On February 26, 2007, our board of directors agreed to amend the terms of outstanding warrants to purchase an aggregate of 452,337 shares of our common stock held by Dr. Dorros and members of his family. The warrants, which had a weighted average exercise price of \$13.76 per share, were due to expire in May 2007. The amendments extend the term of the warrants so that rights to purchase shares expire as follows: 10% in May 2007, 22.5% in May 2008, 22.5% in May 2009, 22.5% in May 2010 and 22.5% in May 2011. In exchange for our agreement to amend the terms of the warrants, Dr. Dorros agreed to purchase a minimum of \$1.0 million of our convertible notes. On May 15, 2007, Dr. Dorros exercised his right to purchase 45,233 shares of common stock pursuant to these warrants.

*Purchase of convertible notes.* On March 30, 2007, the Gerald and Myra S. Dorros Revocable Trust, an entity controlled by Dr. Dorros, purchased \$1.0 million of our convertible notes. Except for the warrant amendment described above, Dr. Dorros did not receive any benefit from this transaction that was not received on a pro rata basis by each other purchaser of our convertible notes.

*Amendment to Registration Rights Agreement.* On January 28, 2008, we and the holders of our outstanding convertible notes, including Dr. Dorros, entered into an Amendment to Notes and Registration Rights Agreement. The amendment amends the convertible notes and that certain Registration Rights Agreement between us and the holders of the convertible notes, dated March 30, 2007, to extend the deadline for us to file a registration statement with the Securities and Exchange

Commission to register the resale of shares of our common stock that are issuable upon conversion of the convertible notes, and to terminate our obligation to file any such registration statement, effective March 30, 2008.

## **OTHER MATTERS**

### ***Other Business***

Neither we nor our board of directors intends to propose any matters of business at the meeting other than those described in this proxy statement. Neither we nor our board of directors know of any matters to be proposed by others at the meeting.

### ***Stockholder Proposals***

For a stockholder proposal to be considered for inclusion in our proxy statement for the annual meeting to be held in 2009, the proposal must be in writing and be received by our Corporate Secretary at our principal executive offices no later than December 17, 2008. If the date of next year's annual meeting is more than 30 days before or after April 16, 2009, the deadline for inclusion of proposals in our proxy statement will instead be a reasonable time before we begin to print and mail our proxy materials. Stockholder proposals must comply with the requirements of Rule 14a-8 of the Securities Exchange Act of 1934, as amended, and any other applicable rules established by the Securities and Exchange Commission, or SEC.

In addition, our bylaws establish an advance notice procedure with regard to stockholder proposals to be brought before an annual meeting of stockholders. For a stockholder's proposal to be brought before our 2009 annual meeting, the stockholder must give written notice to our Corporate Secretary at our principal executive offices not less than sixty (60) days and not more than ninety (90) days prior to the date set for the annual meeting, regardless of any postponements, deferrals or adjournments of that meeting to a later date; provided, that if the 2009 annual meeting is to be held on a date prior to the second Wednesday in June, which in 2009 will be June 10, 2009, and if less than seventy (70) days' notice or prior public disclosure of the date of the annual meeting is given or made, notice by the stockholder to be timely must be given by the close of business on the tenth (10<sup>th</sup>) day following the earlier of the date on which notice of the date of the annual meeting was mailed or the day on which public disclosure was made of the date of the annual meeting. Our bylaws also specify requirements as to the form and content of a stockholder's notice.

### ***Nomination of Director Candidates***

Any proposals to nominate candidates for election to our board of directors must be in writing and include the nominee's name and qualifications for board membership and should be directed to our Corporate Secretary at our principal executive offices. To be timely, a stockholder's notice must be received by our Corporate Secretary within the time specified in our bylaws for stockholder proposals, described above. The notice must contain all information relating to the proposed nominee that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended, or pursuant to any other then existing statute, rule or regulation applicable thereto (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), and must also include information concerning the identity of, and shares of our stock held of record and beneficially by, both the record stockholder giving the notice and the beneficial owner of our stock, if other than the record holder giving notice, on whose behalf the nomination is made.

### ***Where You Can Find Additional Information***

We are required to file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these proxy materials and any other documents we have filed at the Securities and Exchange Commission's Public Reference Room at 100 F Street, N.E., Room 1580, Washington D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the Public Reference Room. Our SEC filings are also available to the public at the SEC's website at <http://www.sec.gov>.

# Corporate Information

## Executive Officers and Senior Management

Michael P. Whitman  
*President and Chief Executive  
Officer*

John P. Gandolfo  
*Chief Financial Officer*

Don Malinouskas  
*Senior Vice President  
Research and Development*

Michael M. Fard  
*Vice President of Operations*

Keith Mintun  
*Senior Vice President  
of Sales*

Greg Jones  
*Senior Vice President  
Regulatory Affairs /  
Quality Assurance*

Patricia Steffan  
*Vice President of Finance*

Peter Reich  
*General Manager  
PMI Deutschland*

Christian Frizzi  
*Managing Director  
PMI France*

Akihisa Akao  
*President  
PMI Japan*

## Directors

Michael P. Whitman  
*Chairman of the Board of  
Directors*

Kenneth S. Abramowitz  
*Managing General Partner  
NGN Capital LLC*

Dr. Gerald Dorros  
*Medical Director  
Dorros Feuer Interventional  
Cardiovascular Disease  
Foundation Ltd.*

James R. Locher III  
*Executive Director  
Project on National Security  
Reform*

John C. Moran  
*Private Investor*

David R. Murray  
*President  
Conmed Electrosurgery,  
a Division of Conmed Corporation*

Lon E. Otremba  
*Principal Managing Partner  
Otremba Management Advisory  
LLC*

## Corporate Offices

Power Medical Interventions, Inc.  
2021 Cabot Boulevard  
Langhorne, Pennsylvania 19047  
Phone: (267) 775-8100  
[www.pmi2.com](http://www.pmi2.com)

## Stock Transfer Agent

Continental Stock Transfer &  
Trust Company  
New York, New York  
Phone: (212) 509-4000

## Independent Auditors

Ernst & Young LLP  
Philadelphia, Pennsylvania

## Corporate Counsel

Foley Hoag LLP  
Boston, Massachusetts

## Stock Listing

The Company's Common Stock  
is traded on The Nasdaq Global  
Market under the symbol  
"PMIL."

## Investor Relations

Please direct inquiries to:  
Power Medical Interventions, Inc.  
Investor Relations  
(267) 775-8100 or  
[IR@pmi2.com](mailto:IR@pmi2.com)





## **Power Medical Interventions®**

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**END**